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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

MARC RICHFIELD, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. POLARITYTE, INC., DENVER LOUGH, DAVID SEABURG, JACOB PATTERSON, PAUL MANN, and RICHARD HAGUE, Defendants.	**AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** Case No. Case No. 2:21-cv-00561-BSJ JURY TRIAL DEMANDED Hon. Bruce S. Jenkins

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Lead Plaintiff Christopher Evans and Named Plaintiff Janet Noel ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against Defendants, allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding PolarityTE, Inc. ("PolarityTE" or the "Company"), analysts' reports and advisories about the Company, interviews with former employees of PolarityTE by Plaintiffs' investigator, documents obtained from a Freedom of Information Act ("FOIA") request from the United States Food and Drug Administration ("FDA"), and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of a class of all person and entities other than Defendants that purchased or otherwise acquired PolarityTE common stock between January 30, 2018 and November 9, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") against the Company and certain of its top officials.

2. After going public via a reverse-merger with a failing gaming company led by serial pump-and-dump fraudsters, PolarityTE began promoting itself as a commercial stage biotechnology company, touting the Company's ability to market and sell its only product,

SkinTE, without first obtaining premarket approval from the FDA or going through the laborious process of clinical trials. In reality, PolarityTE only obtained the ability to sell their product without FDA approval by improperly registering their product under a regulation for which it was not eligible. Once the FDA caught up and told the Company that they would have to stop selling SkinTE and obtain premarket approval, Defendants repeatedly misled investors by claiming that the Company was doing everything they could to submit the SkinTE application to the FDA, including doing the work necessary to meet FDA standards for chemistry, manufacturing, and control ("CMC"). This was false. In truth, the Company had ignored CMC issues for years. These CMC issues eventually caused the FDA to place the SkinTE application on clinical hold, thereby delaying any FDA approval for the product.

3. SkinTE is a Human Cell, Tissue, and Cellular and Tissue-Based Product ("HCT/P"). HCT/Ps are products consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer to a human recipient. SkinTE is intended to repair, reconstruct, replace, and supplement skin in patients who have certain wounds, burns, surgical reconstruction events, scar revision, or dysfunctional skin grafts.

4. The FDA sets the regulatory framework for HCT/Ps based on a risk-based approach. For SkinTE, there were two relevant regulatory pathways: (1) regulation under Section 361 of the Public Health Service Act (the "PHS Act") (the "Section 361 pathway"); or (2) regulation under Section 351 of the PHS Act (the "Section 351 pathway").

5. The Section 361 pathway allows for immediate commercial use without FDA review for safety and effectiveness of the product. HCT/Ps may be regulated under the Section 361 pathway if they: (1) are minimally manipulated; (2) are intended for homologous use only (meaning the HCT/P performs the same basic function as the cells or tissues that it is meant to

repair or replace); and (3) do not involve cells and tissues combined with other articles (subject to certain exceptions not relevant here). These so called "361 HCT/Ps" are exempt from premarket review and approval requirements because the FDA considers them low risk products.

6. The Section 351 pathway, on the other hand, requires FDA approval of the product before any commercial use. This typically means the 351 HCT/P manufacturer must submit an investigational new drug application ("IND" or "IND application"), which allows the manufacturer to begin clinical trials on humans. The clinical data gathered during this process is then used to support a Biologics License Application ("BLA"). The FDA will approve the BLA only after the manufacturer proves that the product meets FDA standards designed to ensure the "continued safety, purity, and potency" of the product. This process is long and expensive.

7. To avoid the lengthy approval process under the Section 351 pathway, Defendants attempted to take advantage of the Section 361 pathway. Defendants registered SkinTE as a 361 HCT/P—without consulting the FDA or seeking advice prior to its registration—ang began selling SkinTE immediately.

8. But Defendants knew that SkinTE was not properly registered under Section 361. For a product to be registered under Section 361, it must be subject to "minimal manipulation," meaning "that the processing of the HCT/P does not alter the original relevant characteristics of the tissue." But the SkinTE process alters the relevant characteristics of skin. The process of creating SkinTE starts with a skin sample from a patient. The sample is then shipped to the Company's manufacturing facility, where it is turned into a white paste that is sent back to the patient in a syringe. This process clearly alters the original skin sample. The paste is no longer a protective layering like the original skin sample, nor does the paste retain skin's dense, strong, and flexible layer of tissue. The SkinTE process also violated Section 361's requirement that the

manufacturing of the 361 HCT/P "does not involve the combination of the cells or tissues with another article." During the SkinTE process, the skin sample is mixed with other components such as scaffolding and growth factor receptor ligands. These additions are clearly prohibited under the Section 361 pathway.

9. Despite knowing that SkinTE was not properly registered under Section 361, Defendants touted the Company's ability to market and sell SkinTE under the Section 361 pathway. This allowed Defendants to portray the Company as a commercial stage biotech company when, in reality, the Company was still a developmental stage company.

10. Defendants touted this strategy to investors, portraying it as fundamental to the Company's value. Defendants repeatedly told investors that the Section 361 pathway was one of the Company's "competitive strengths" and that the commercial launch of SkinTE was key to the Company's growth. Meanwhile, Defendants downplayed the risk that the FDA would disagree with them and require the Company to seek FDA approval under the Section 351 pathway.

11. Behind the scenes, employees were not allowed to voice concerns about the Company's regulatory status. Defendant Lough, the CEO at the time, refused to listen to anyone that disagreed with him that SkinTE was a 361 HCT/P and silenced any opposition through intimidation. According to one former employee, if anyone disagreed with Lough about the 361 registration, Lough would "chop their head off."

12. In August 2019, the Board abruptly removed Lough as CEO without any explanation. At that point, employees were finally able to openly discuss that SkinTE was registered under the wrong section. Internal discussions among senior employees, including directors and vice presidents, took place throughout the summer and fall of 2019. By December 2019, the conversations turned into distinct planning for the transition to regulatory approval under

the Section 351 pathway. Despite this, Defendants continued misleading investors about the Company's ability to market and sell SkinTE as a 361 HCT/P, while downplaying the risks involved in switching to the Section 351 pathway.

13. On April 21, 2020, the FDA advised Defendants that SkinTE was not properly registered under Section 361. This meant that SkinTE would have to be approved under the Section 351 pathway before the Company could continue selling it. However, Defendants continued misleading investors. Defendants told investors that the Company still believed SkinTE was properly registered as a 361 HCT/P and led investors to believe that the Company could continue selling SkinTE as a 361 HCT/P indefinitely. But the truth was the Company could only sell SkinTE for a limited period of time.

14. Defendants could continue selling SkinTE for a limited time only because the FDA had an enforcement discretion policy in place for all HCT/P manufacturers. This grace period gave HCT/P manufacturers the freedom to market their product while engaging with the FDA to determine if their product was a 361 HCT/P or a 351 HCT/P. If the product was a 351 HCT/P, this period gave manufacturers time to prepare for filing an IND and BLA. But all HCT/P manufacturers knew that the FDA's enforcement discretion period expired on May 31, 2021. At this point, 351 HCT/Ps like SkinTE would be subject to normal FDA approval requirements, meaning manufacturers could not market or sell their 351 HCT/P without a license.

15. Thus, Defendants knew that they would have to stop all commercial sales by May 31, 2021, and that their financial condition would be negatively affected (since SkinTE was their only commercially available product). However, Defendants continued misleading investors into believing that the Company could continue selling SkinTE indefinitely. Defendants falsely told investors that following the end of the enforcement discretion policy, the Company "may" have to

stop selling SkinTE. This was false in that it presented the situation as one of uncertainty. The Company was unambiguously required to stop selling SkinTE at the end of the enforcement discretion policy. Defendants also falsely told investors it was only "possible" that SkinTE sales would not contribute to the Company's capital resources in 2022. The FDA's enforcement discretion period ended on May 31, 2021; thus, the Company could not sell SkinTE in 2022. In other words, it was not a possibility, but a fact, that SkinTE sales would not contribute to the Company's capital resources in 2022.

16. The truth was revealed on May 13, 2021 when—only three weeks before the enforcement discretion policy was set to expire—Defendants finally disclosed that the Company would have to cease all commercial sales of SkinTE by the end of the month and, as a result, would have to wind down commercial operations until the Company obtained formal FDA approval for SkinTE. On this news, PolarityTE's share price plummeted, closing down 21% from the previous day.

17. PolarityTE then pivoted backwards to being a developmental stage company and told investors that the Company was in the process of preparing an IND application with the FDA for SkinTE. However, they continued to mislead investors by repeatedly telling investors that they expected to file the SkinTE IND application in the second half of 2021 and that they remained "on track" for this timeline, even stating that they were "working diligently to accelerate that timeline as much as possible." This was misleading because Defendants had ignored work that was necessary to successfully submit an IND.

18. An IND application requires, among other things, preclinical data, and information about the company's proposed protocols and CMC items. Defendants falsely reassured investors that they were completing "the necessary CMC and preclinical work to satisfy FDA requirements."

Defendants also told investors that the Company was "making excellent progress" with the CMC work for the IND application and that this work would allow the Company "to validate and implement a matrix of product release assays to meet FDA requirements.

19. But in truth, Defendants were not doing the necessary CMC work to satisfy FDA requirements. In fact, they had ignored significant CMC issues for years.

20. In July 2018, the FDA identified several CMC issues during their inspection of the Company's manufacturing facility in Salt Lake City, Utah. After the inspection, the FDA sent the Company's senior management a Form 483 listing violations the FDA observed during the inspection. The FDA also discussed the violations with the Company's senior management, meaning Defendants were aware of and fully understood the CMC violations.

21. Plaintiffs obtained the FDA Form 483 as part of a FOIA request. The Form 483 shows that the CMC issues identified by the FDA in July 2018 were the very same issues that would cause the FDA to place the SkinTE IND on clinical hold in August 2021, meaning Defendants had ignored the CMC issues for over three years.

22. As a result, Defendants' statements that they were completing "the necessary CMC and preclinical work to satisfy FDA requirements" for the IND application were false and misleading because they did not disclose that the Company ignored known CMC issues. Because these CMC issues needed to be resolved prior to submitting the IND, the Company was not "on track" to submit the SkinTE IND, since it was inevitable that the FDA would place the IND on clinical hold until the Company resolved the CMC issues.

23. The truth was partially revealed on August 24, 2021, when the Company disclosed that the FDA placed the SkinTE IND on clinical hold because of CMC items that needed to be

addressed. The Company did not disclose the specific CMC issues. On this news, the Company's stock fell by 9.52%

24. The truth was fully revealed on November 10, 2021, when Defendants disclosed the specific CMC issues that needed to be addressed before the FDA would lift the clinical hold. Defendants disclosed that "[t]he clinical hold issues that must be resolved before the clinical hold can be lifted involve, our proposed potency assay; drug product dosage, storage, shipping, and release specifications; antibiotics residuals; bacteriostasis and fungistasis testing; and delivery device." On this news, the Company's stock fell by 10.45%. Through the FOIA request, Plaintiffs were able to determine that many of these CMC issues were the same issues identified by the FDA in July 2018, meaning Defendants were aware of these issues but did nothing to resolve them.

25. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's stock, Plaintiffs and other Class Members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

26. The claims assert herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

28. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), because many of the false and misleading statements were made in or issued from this District, and PolarityTE's principal executive offices are located within this Judicial District.

29. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

30. Plaintiffs acquired PolarityTE securities at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures. Lead Plaintiff Christopher Evans's PSLRA certification was previously filed with the Court (Dkt. No. 25-3) and is incorporated by reference. Named Plaintiff Janet Noel's PSLRA certification is attached as an Exhibit to this Complaint.

31. Defendant PolarityTE is a Delaware corporation with principal executive offices located at 1960 S. 4250 West, Salt Lake City, Utah 84104. PolarityTE's common stock trades in an efficient market on the NASDAQ under the ticker symbol "PTE."

32. Defendant Denver Lough ("Lough") was the founder of PolarityTE and inventor of SkinTE. He served as the Company's Chief Executive Officer ("CEO") and Chairman from December 1, 2016 until August 2019. Prior to serving as CEO of PolarityTE, Lough was a Plastic & Reconstructive Surgery House Staff Officer at Johns Hopkins University School of Medicine, Department of Plastic & Reconstructive Surgery.

33. Defendant David Seaburg ("Seaburg") joined PolarityTE in August 2018 as a director and subsequently joined the management team in January 2019, serving as President of Corporate Development until August 2019, when he joined the Office of the Chief Executive, before being named Chief Executive Officer in April 2020. He served as PolarityTE's CEO from April 2020 through August 2021, and currently serves as a Director and Chair of the Board's

Strategic Review Committee. Prior to joining PolarityTE, Seaburg spent over 20 years at Cowen in both Equity Sales Trading and Trading. In 2006, Seaburg was named Head of Sales Trading and appointed to the firm's Equity Operating Committee. Seaburg was a CNBC Fast Money Contributor and provided regular on-air commentary for the network.

34. Defendant Jacob Patterson ("Patterson") is the Company's Chief Financial Officer ("CFO"). He joined PolarityTE in January 2018 and served as Vice President of Finance. He then served as the Company's Interim CFO from March 31, 2020 until August 2021, when he assumed the role of CFO. Prior to his employment with PolarityTE, Patter was a finance director at Gamestop and Thermo Fisher Scientific.

35. Defendant Paul Mann ("Mann") served as the Company's CFO from June 2018 until March 31, 2020. From August 2013 to March 2016, Mann served as an analyst with Soros Fund Management, and prior to that, Mann was an analyst and portfolio manager with Lodestone Natural Resources and UBS from September 2011 to March 2013.

36. Defendant Richard Hague ("Hague") is the Company's CEO and President. He joined PolarityTE in April 2019 as Chief Operating Officer ("COO") and served in the Office of the Chief Executive beginning in August 2019 until April 2020, when he began serving as the Company's President in addition to COO. He was appointed as the Company's CEO in August 2021. Prior to his employment with PolarityTE, Hague was the Chief Commercial Officer of Anika Therapeutics.

37. Defendants Lough, Seaburg, Patterson, Mann, and Hague are sometimes referred to herein as the "Individual Defendants."

38. PolarityTE is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all the wrongful acts complained of herein were carried out within the scope of their employment.

39. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

40. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

IV. BACKGROUND

A. Company Background

41. PolarityTE, headquartered in Salt Lake City, Utah, is a biotechnology company that develops regenerative tissue products and biomaterials. The Company operates through two segments: regenerative medicine products and contract services.

42. Defendant Lough founded the Company and invented the PolarityTE regenerative medicine and tissue engineering platform. The PolarityTE platform was meant to produce a range of products for different types of tissue.

43. On December 1, 2016, the Company announced that it would go public via a reverse merger with Majesco Entertainment, a company that had previously created video games. At the time of the merger, Defendant Lough owned 100% of the issued and outstanding shares of capital stock of PolarityTE.

44. In January 2017, Majesco Entertainment changed its name to PolarityTE, Inc. On June 23, 2017, PolarityTE sold all the assets and liabilities of Majesco Entertainment's gaming business.

45. Following the merger, Defendant Lough replaced Barry Honig as the Company's CEO. Honig resigned as a member of the Board of Directors effective February 8, 2017. Michael Brauser was the Chairman of Majesco but also resigned as a director of PolarityTE on February 8, 2017. John Stetson, who had been the CEO of Majesco, remained with PolarityTE in the same role.

46. In September 2018, the SEC charged Honig, Stetson, Brauser, and others for their role in pump-and-dump schemes of three public companies. According to the SEC, Honig and his associates bought stock in three small companies, controlled the firm's managements, and planted promotional articles about them before unloading their shares. These schemes "generated over $27 million from unlawful stock sales and caused significant harm to retail investors who were left holding virtually worthless stock."

47. The SEC alleged that, "in each scheme, Honig orchestrated his and his associates' acquisition of a large quantity of the issuer's stock at steep discounts, either by acquiring a shell and executing a reverse merger or by participating in financings on terms highly unfavorable to the company." Then, "after securing a substantial ownership interest in the companies," the Group "engaged in illegal promotional activity and manipulative trading to artificially boost each issuer's stock price and to give the stock the appearance of active trading volume." When the price of the stock was artificially inflated, "Honig and his associates [] dumped their shares into the inflated market, reaping millions of dollars at the expense of unsuspecting."

48. In October 2018, the SEC subpoenaed PolarityTE, seeking documents related to "(i) communications and agreements between us and, among others, John Stetson, Barry Honig and Michael Brauser, (ii) the transaction pursuant to which Majesco Entertainment Company acquired PolarityTE NV and our current regenerative medicine business, (iii) the performance of

and communications with regulators regarding SkinTE, our lead product, and (iv) any promotion of the Company or its securities."

49. On March 4, 2019, the SEC sent a copy of the formal order of investigation of the Company with respect to possible violations of the federal securities laws. Since then, the SEC has sent the Company four additional subpoenas for documents concerning "(i) the circumstances under which the Company placed Denver Lough, former Chief Executive Officer, and Naveen Krishnan, former Vice President of Analytics, on paid administrative leave, (ii) termination and separation agreements with former employees, and (iii) certain commercialization metrics included in Company disclosures."

50. In July 2019, Honig agreed to a partial final judgment with the SEC whereby Honig agreed to be barred from offering of penny stocks and owning more than 4.99% of any penny stock. Honig also agreed to other injunctive relief, including that he is "permanently restrained and enjoined from violating, directly or indirectly, Section 10(b) of the [Exchange Act] and Rule 10b-5 promulgated thereunder." As part of the settlement, Honig agreed to leave his respective liability for monetary relief to be determined later. Upon information and belief, the monetary relief against Honig has yet to be decided or announced.

51. In March 2020, Stetson and Brauser agreed to a settlement with the SEC. Under the terms of the settlement, Stetson agreed to disgorge $837,509.98 plus $157,159.30 prejudgment interest, and will pay a civil penalty of $160,000, which together total $1,154,669.28. Stetson and his company, Stetson Capital Investments Inc., are barred from involvement in penny stock offerings for a decade. Brauser agreed to disgorge $844,914.32 with prejudgment interest of $170,853.84, and will pay a $160,000 civil penalty, which together total $1,175,768.18. Brauser

and his company, Grander Holdings Inc., are also permanently barred from being involved in any penny stock offering.

52. PolarityTE fired Stetson in response to the SEC charges, but Honig and Brauser remained as large stakeholders of the Company. According to the Company's Annual Report for the fiscal year ended December 31, 2019, the two controlled over 10% of the company's shares combined.

B. SkinTE

53. The Company's first regenerative tissue product is SkinTE, which is intended for the repair, reconstruction, replacement, and supplementation of skin in patients who have a need for treatment of acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts.

54. The core technology of SkinTE is minimally polarized functional units ("MPFUs"). MPFUs are multi-cellular segments created from a piece of the patient's healthy skin.

55. SkinTE is meant primarily to replace the current standard of care: split-thickness skin grafts ("STSGs"). During a STSG, the surgeon will remove a thin layer of skin from one part of the patient's body (known as the donor site) and use it to close the surgical site that needs to be covered (the recipient site). STSGs, which involve harvesting the entire epidermis but only partial dermis, have the advantage of being from the patient and not requiring a full-thickness harvest, which require harvesting complete epidermis and dermis. STSGs have been used for many years, so doctors have experience with them and trust in the procedures. However, they can sometimes lead to poor post-operative quality of life for patients, as the grafts do not have the fat layer, hair follicles, sweat, and sweat and sebaceous glands.

56. PolarityTE claims that SkinTE produces results that are superior to STSGs and synthetic skin substitutes. According to the Company's 2020 Annual Report on Form 10-K, "SkinTE allows the patient to regenerate full-thickness, three-dimensional skin (similar to a FTSG) by contributing a much smaller skin sample, while reducing the scarring and morbidities associated with STSGs." The Company claims that SkinTE can "provide[] complete and durable wound closure with the regenerated tissue having many of the important characteristics of native skin such as pliability, strength, sensation, ability to sweat, and hair growth."

57. The process for SkinTE starts with the collection of a skin sample from the patient. The skin sample is then shipped in a temperature-controlled shipping box to the Company's manufacturing facility in Salt Lake City. There, the harvested skin sample is used to manufacture SkinTE into a white pasty medium that goes back to the doctor in a syringe. The doctor then prepares spreads SkinTE evenly across the entire surface of the wound. SkinTE engrafts within the wound and once integrated with the wound bed, the product expands and regenerates skin across the entire surface.

C. Patents for SkinTE

58. From the start, the Company has sought to protect its intellectual property with patents, seeking U.S. and foreign patent protection for a variety of technologies, including its MPFU technology and Biological Sample Harvest and Deployment Kits. According to the Company's Annual Report for the Fiscal Year Ended December 31, 2020, the Company has "a number of patents issued and pending applications allowed in the United States and abroad related to our MPFU technology, including U.S. Patent No. 10,926,001 which issued on February 23, 2021. U.S. Patent No. 10,926,001 was filed on November 30, 2015 as Application No. 14/954,335."

D. Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

59. In the United States, HCT/Ps, like SkinTE, are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and the Public Health Service Act (the "PHS Act").

60. HCT/Ps are defined in 21 CFR 1271.3(d) as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, and semen or other reproductive tissue.

61. HCT/Ps are subject to varying degrees of regulation by the FDA, depending on if they fall solely within the scope of Section 361 of the PHS Act (42 U.S.C. § 264) or if they are regulated as drugs, devices, or biological products under Section 351 of the PHS Act (42 U.S.C. § 262) or the FD&C Act.

62. HCT/Ps that are regulated *solely* under Section 361 (referred to herein as a "361 HCT/P" or a "361-product") are exempt from premarket review and approval by the FDA. In other words, the Section 361 pathway allows a company to market and sell a product without the lengthy, formal FDA approval process.

63. The FDA applies a four-part test to determine if an HCT/P is an HCT/P regulated solely under Section 361, and thus exempt from the IND and premarket review and approval requirements of 351 HCT/Ps. An HCT/P is regulated solely under Section 361 of the PHS Act and 21 CFR 1271 if it meets all of the following criteria:

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

- Either:
  (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
  (ii) HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
    (a) Is for autologous use;
    (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
    (c) Is for reproductive use.

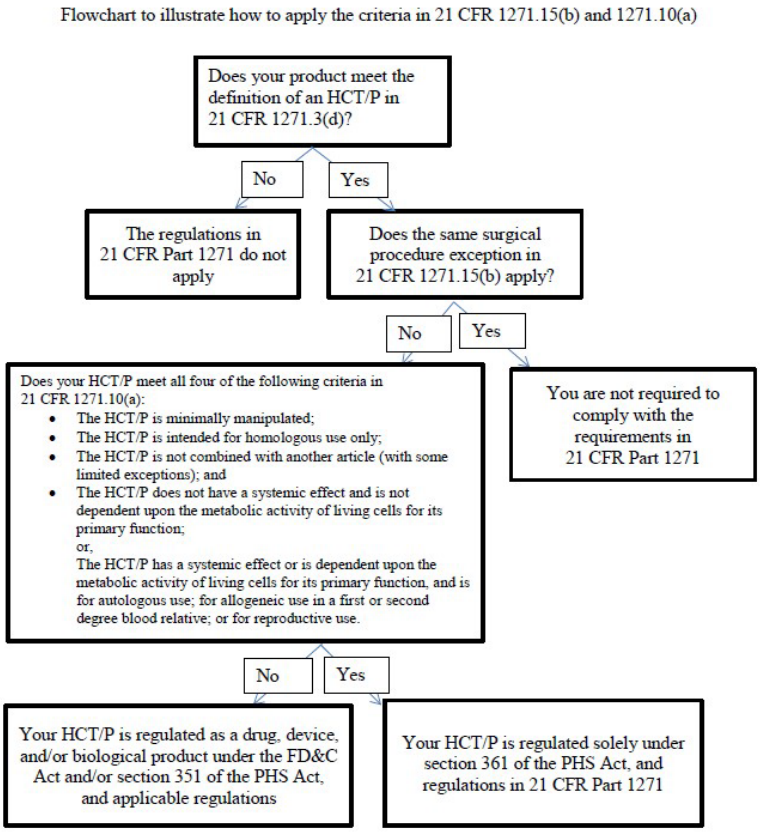
See 21 CFR 1271.10(a).

64. Product manufacturers are not required to consult with the FDA and can market their products based on their own conclusion that their product meets the 361 HCT/P criteria.

65. If the HCT/P does not meet the criteria set out in 21 CFR 1271.10(a), the FDA will regulate the HCT/P as a drug, device, and/or biological product under Section 351 of the PHS Act or the FD&C Act (referred to herein as a "351 HCT/P" or a "351-product").

66. Manufactures of 351 HCT/Ps are subject to traditional premarket and postmarket requirements. Manufacturers of 351 HCT/Ps must complete extensive clinical trials, which must be conducted pursuant to an effective IND. In addition, these 351 HCT/Ps require approval of a biologic license application ("BLA"), and their manufacture must comply with current good manufacturing practices ("CGMPs"). The FDA issues such licenses only after a determination that the establishment and the biological product meet the applicable requirements to ensure the continued safety, purity, and potency of such products (21 CFR 601.2(d)).

67. In guidance provided to HCT/P manufacturers, the FDA provides the following flowchart to illustrate how manufacturers and healthcare provides should apply the 21 CFR 1271.10(a) criteria to determine if their product meets the requirements of a 361 HCT/P or should be regulated as a 351 HCT/P:



68. To lawfully market a 351 HCT/P, a biologics license must be in effect (PHS Act 42 U.S.C. 262(a)). Such licenses are issued only after a determination by the FDA that the manufacturing facility and the biological products meet the applicable requirements to ensure the continued safety, purity, and potency of such products. *See* 21 CFR 601.2(d). Manufacturers must demonstrate to the FDA the safety and potency of their products through clinical trials. Before clinical trials can commence, the sponsor must have an Investigational New Drug ("IND")

application in effect in accordance with the FD&C Act (21 U.S.C. 355(i)) and FDA regulations (21 CFR Part 312 and 21 CFR 601.21).

69. The IND application must contain information in three areas: (1) preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans; (2) manufacturing and CMC information required to assure product safety, identity, quality, and strength (including potency) of the investigational product; and (3) detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Once an IND application is approved, the manufacturer may begin clinical testing.

70. If the data generated by the clinical studies demonstrates that the product is safe and effective for its intended use, it is submitted as part of a marketing application. A Biologics License Application ("BLA") is required for biological products like SkinTE. FDA approval of a BLA is granted by the issuance of a biologics license. Only after the biologics license is approved may the manufacturer market the new product.

71. In November 2017, the FDA announced a temporary compliance and enforcement discretion policy, which provided for a three-year period of enforcement discretion for all HCT/Ps. This "grace period" was meant to give all manufacturers time to engage with the FDA to determine whether they met the four requirements to market their products solely under Section 361, or if they needed to file an IND application or marketing application with the FDA, and if so, time to prepare and submit an application. This grace period applied automatically to all HCT/P manufacturers.

72. During this grace period, manufacturers could obtain a recommendation or decision from the FDA regarding the classification of an HCT/P by either: (1) requesting a recommendation from the Tissue Reference Group ("TRG"); (2) submitting a Request for Designation ("RFD") to

the Office of Combination Products ("OCP"); or (3) submitting a Pre-RFD to OCP. The TRG recommendation process is informal and results in non-binding responses. The Pre-RFD process also generates non-binding, preliminary feedback. However, submitting an RFD results in a formal agency decision regarding the classification of the HCT/P.

73. Thus, this period gave HCT/P manufacturers time to prepare for an IND application and BLA while still having the ability to sell their product under the limited enforcement discretion policy.

74. The enforcement discretion policy was initially planned to end in November 2020. However, on July 20, 2020, the FDA extended the enforcement discretion period to May 31, 2021 due to challenges presented by the COVID-19 public health emergency.

E. PolarityTE Incorrectly Registers SkinTE as a 361 HCT/P

75. On August 14, 2017, the Company registered SkinTE as a 361 HCT/P, meaning the Company claimed the product was exempt from the FDA's pre-market clearance and clinical study requirements and could be immediately listed for commercial use. Under this pathway, the Company launched a commercial rollout of SkinTE in November 2017.

76. The Company did not consult the FDA (neither the TRG nor the OCP) when making its determination that SkinTE was properly registered as a 361 HCT/P.

77. Regulating SkinTE as a 361 HCT/P was vitally important to the Company's value proposition. For example, in the Company's Annual Report for the fiscal year ended October 31, 2017, filed on Form 10-K with the SEC on January 30, 2018 (the "2017 10-K"), the Company promoted the 361-pathway as one of its "competitive strengths," stating, in pertinent part:

> ***Efficient Regulatory Pathway***. We believe our products and product candidates, including SkinTE, are appropriately regulated by the FDA as 361 HCT/Ps, which provides us with the potential to register and list products with the FDA, and begin commercializing quickly and efficiently.

> Unlike products regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and/or the Public Health Service Act as drugs, devices, or biologics, which require multi-phase clinical trials and premarket approvals, our SkinTE product is regulated by the FDA as human cells or tissues intended for implantation. We are developing our additional pipeline candidates to be regulated as 361 HCT/Ps as well. 361 HCT/Ps do not require premarket approval or other premarket authorization and may be lawfully marketed for appropriate human use in the United States following registration with the FDA.

78. Similarly, in the 2017 Form 10-K, the Company explained that "the full commercial launch of SkinTE" was key to the Company's growth strategy.

F. SkinTE Was Not a 361 HCT/P

79. However, SkinTE did not meet the requirements to be regulated solely under Section 361. The SkinTE manufacturing process involved manipulating the skin and combining it with other articles to create a paste that would be applied to a patient's wound. The manipulation of the skin and addition of other articles are both prohibited under Section 361.

80. In order to qualify as a 361 HCT/P, a product must be "minimally manipulated." As defined in 21 CFR 1271.3(f), minimal manipulation means:

> (1) For structural tissue, ***processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement***; and (2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(Emphasis added).

81. In this case, the structural tissue definition applies. SkinTE does not meet the definition of "minimally manipulated" of structural tissue because the procedure behind SkinTE no longer allows the product to maintain "the original relevant characteristics." During the manufacturing process, the skin is processed into a paste. Thus, it is no longer a protective covering, nor does the paste retain skin's dense, strong, and flexible layer of tissue.

82. On November 16, 2017, the FDA issued guidance to HCT/Ps outlining the requirements for minimal manipulation and homologous use.[1] The FDA Guidance provided the following example of processing skin that is more than minimal manipulation:

> A manufacturer processes skin by removing the epidermis and then grinding the dermis into particles. The HCT/P generally is considered more than minimally manipulated because the processing alters the original relevant characteristics of skin related to its utility as a protective covering.

83. Under this guidance, SkinTE is clearly more than minimally manipulated if the FDA considers "grinding the dermis into particles" to be more than minimal manipulation, since SkinTE is transformed from a skin sample into a white paste.

84. SkinTE also fails to meet Section 361's requirement that the manufacturing "does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P." 21 CFR 1271.10(a). This requirement means that products are not allowed to be mixed with a carrier during manufacture, nor are they allowed to be treated with supplements such as growth factors. However, the Company's own patent, US 2016/0151540 A1, shows that the SkinTE process uses growth factors:

> [0014] The invention provides in a first embodiment a minimally polarized micro-aggregate multi-cellular composition including isolated living LGR expressing cells and a multi-dimensional support selected from the group consisting of ***scaffolding***, collagen, matrix, particle, and fiber.
>
> [0015] The invention provides in a further embodiment to the previous embodiment a minimally polarized micro-aggregate multi-cellular composition including isolated living LGR expressing cells and a multi-dimensional support selected from the group consisting of ***scaffolding,***

[1] Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use ("FDA Guidance"), *available at* https://www.fda.gov/media/109176/download.

> collagen, matrix, particle, and fiber where the LGR expressing ***cells are supplemented with growth factors*** and where the LGR expressing cells are selected from the group consisting of LGR4, LGR5 and LGR6.
>
> [0016] The invention provides in a further embodiment to any of the previous embodiments a minimally polarized micro-aggregate multi-cellular composition including isolated living LGR expressing cells and a multi-dimensional support selected from the group consisting of ***scaffolding***, collagen, matrix, particle, and fiber where the LGR expressing ***cells are supplemented with migratory/recruiting analytes*** and the LGR expressing cells being selected from the group consisting of LGR4, LGR5 and LGR6.
>
> [0017] The invention provides in a further embodiment to any of the previous embodiments a minimally polarized micro-aggregate multi-cellular composition including isolated living LGR expressing cells and a multi-dimensional support selected from the group consisting of scaffolding, collagen, matrix, particle, and fiber where the LGR expressing cells are supplemented with ***LGR specific binding elements selected from the group consisting of ligand families, R-spondin, EDGF, PDGF, Wnt, VEGF***, and antimicrobial peptides and where the LGR expressing cells are selected from the group consisting of LGR4, LGR5 and LGR6.

(Emphasis added).

85. The bolded sections above shows that the patent filing by PolarityTE consists of claims which include combinations with other components such as scaffolding and growth factor receptor ligands. These additives are not allowed for products registered under Section 361, which only allow for the addition of "water, crystalloids, or the sterilizing, preserving, or storage agent."

86. Lough published two papers that explained his invention uses growth factors. In 2013, Lough published a paper titled, "Stimulation of the follicular bulge LGR5+ and LGR6+ stem cells with the gut-derived human alpha defensin 5 results in decreased bacterial presence, enhanced wound healing, and hair growth from tissues devoid of adnexal structures." In 2016, Lough published a paper titled, "Transplantation of an LGR6+ Epithelial Stem Cell-Enriched Scaffold for Repair of Full-Thickness Soft-Tissue Defects: The In Vitro Development of Polarized Hair-

Bearing Skin." Both papers explain that the fundamental research behind the PolarityTE patents involve culturing with fetal bovin serum—which contains a collection of growth factors—as well as endothelial growth factor and basic fibroblast growth factor. The conditions also call for the addition of insulin and hydrocortisone, two growth factors that would also be outside of the FDA's guidance for 361 HCT/Ps.

87. Moreover, products similar to SkinTE are registered under Section 351 and have gone through the IND application and BLA process before entering the market. According to an August 1, 2018 article from *Seeking Alpha* titled "PolarityTE: Paradigm Shift or Expensive Skin Graft?" Vericel's product Epicel is a close competitor to SkinTE and has been on the market for 20 years. According to the article, the process for Epicel is similar to SkinTE: "With Epicel, a surgeon sends off two stamp size donor samples of the patient's skin. From this, Vericel can grow enough skin to cover an entire patient." The *Seeking Alpha* article explains that Epicel "went through the more stringent 351 process through the FDA, meaning it had to obtain PreMarket Approval and underwent series of clinical trials and human testing."

G. Lough Silenced Discussions Regarding Risks

88. Defendant Lough knew that SkinTE did not qualify as a 361 HCT/P. As the inventor, he understood that the manufacturing process manipulated the skin in a way that was not allowed under Section 361. However, Lough silenced any opposition. He intimidated employees who expressed concerns over SkinTE's registration status and refused to discuss the possibility that SkinTE was registered under the wrong section.

89. This was confirmed by AW1.[2] AW1 was the Senior Director of Clinical and Translational Science at PolarityTE from June 2018 until June 2020. During her time at PolarityTE, she reported to the Chief Medical Officer, including Ned Swanson. Dr. Swanson was the Co-Founder of PolarityTE, serving as the Company's Chief Operating Officer from December 2016 to April 2019, the Chief Translational Medicine Officer from April 2019 to January 2020, and the Chief Medical Officer from January 2020 to May 2021. AW1 had a relationship with Defendant Lough for years before PolarityTE, working together at Georgetown Medical Center. When Lough founded PolarityTE, he asked AW1 to join him at the Company. AW1 said that Lough refused to consider the possibility that SkinTE was not properly registered as a 361 HCT/P. According to AW1, Lough was "pretty arrogant about what their regulatory status was." She said that one investor who "had taken a massive position" and "had the ear of important people at the Company" tried to convince Lough to have the Company conduct clinical trials for an eventual BLA, just in case the FDA later disagreed with the 361 HCT/P classification." But Lough did not want to hear it. According to this AW1, Lough did not like to hear anyone tell him the product did not fit the 361 category and, if anyone disagreed with him, Defendant Lough would "chop their head off."

90. Thus, even though the Company publicly issued generic warnings that the FDA could "disagree[] with our interpretation," that SkinTE was a 361 HCT/P, the reality was that the Company did not take that risk seriously. AW1 said that Lough was adamant that SkinTE was a 361 HCT/P and "was very head strong from the very beginning about not pursuing the BLA, and sticking to their guns about being a 361 [HCT/P]."

[2] All references to AW refer to anonymous witnesses contacted by Plaintiffs' investigator. All references to AW use the pronoun "she" regardless of gender to preserve anonymity.

H. Board of Directors Abruptly Removes CEO Lough

91. On May 31, 2019, independent members of the Board of Directors of PolarityTE, representing a majority of the Board, placed Defendant Lough, the Company's founder, CEO, and Chief R&D Officer, on indefinite paid administrative leave. However, Lough continued to serve as Chairman of the Board and a director of the Company.

92. That same day, the Company established the Office of the Chief Executive, consisting of a team of Richard Hague, Chief Operating Officer, Paul Mann, Chief Financial Officer, and David Seaburg, President of Corporate Development. According to the Company's May 31, 2019 Current Report, filed with the SEC on Form 8-K, "The Office of Chief Executive will address the immediate business needs of the Company as the Company transitions from product development of SkinTE™ to product commercialization, but will be replaced by a more traditional management structure in the future as the goals set for the Office of Chief Executive advance."

93. On August 12, 2019, Lough sent the Company a written demand claiming that actions taken by the Board of Directors to place him on administrative leave was wrongful and demanding that the Company rescind their actions within 30 days.

94. On August 21, 2019, the Company and Lough reached a settlement, and on August 26, 2019, Lough resigned from his position with the Company. On August 26, 2019, Seaburg was appointed to the position of President of PolarityTE.

95. The Board never disclosed why it removed Lough from his position as CEO or placed him on administrative leave.

96. After Lough's abrupt firing, the SEC sent the Company a subpoena for documents concerning the circumstances under which the Company placed Lough on paid administrative leave.

97. After Lough's termination, employees were finally able to have open discussions that SkinTE was registered under the wrong section. This was confirmed by AW3, who was a Quality Engineer at PolarityTE from January 2019 to March 2020 and worked at the company's headquarters in Salt Lake City. During her employment at PolarityTE, she reported to the Executive Director of Quality. AW3 stated that employees began having discussions sometime in the summer or fall of 2019 that SkinTE might be registered under the "wrong section" and the Company might need to submit to the FDA for a different regulatory status. According to AW3, these discussions were going on among directors and vice presidents in Regulatory, Quality, Manufacturing, and R&D, who attended meetings to discuss the regulatory change. By December 2019, the conversation had moved into more distinct planning. According to this former employee, by this point, "it was not, 'we may have to do [it].' It was more to the side of, 'we will probably have to.'"

98. All the while, the Company issued public statements touting its ability to market and sell SkinTE under Section 361.

99. On March 31, 2020, the Company's Board dissolved the Office of the Chief Executive. According to the Current Report, filed on April 1, 200 with the SEC on Form 8-K, "The Board believes the OCE has performed its function to effectuate a transition in the operations of PTE, and now is the time to adopt a more conventional management structure to advance PTE's operational and strategic objectives."

100. As a result, as of March 31, 2020, Defendant Seaburg served as the CEO, Defendant Hague remained as the COO, and Defendant Patterson, PolarityTE's Vice President of Finance, was appointed interim CFO.

101. Then, in April 2020, Defendants disclosed that the FDA advised the Company that SkinTE was not properly registered under Section 361 and that the Company should stop marketing SkinTE as a 361 HCT/P. This meant that after the enforcement discretion policy ended, PolarityTE would have to stop all commercial sales of SkinTE until they successfully submitted an IND application and BLA for SkinTE.

I. FDA's July 2018 Inspection of PolarityTE's Facility

102. In July 2018, the FDA inspected PolarityTE's manufacturing facility in Salt Lake City.

103. The inspection analyzed conditions that are relevant under both the Section 361 pathway and the Section 351 pathway. This fact was confirmed by AW2, who worked at the Company from September 2018 to May 2021 as a Sales Manager and Director of Strategic Sales and reported to the Vice President of Sales. AW2 heard from other employees that the FDA inspection was done "under both 361 and a BLA." AW2 said the inspection analyzed "everything for a BLA application and for a 361."

104. Following the inspection, the FDA issued a Form 483 noting several significant violations. An FDA Form 483 "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute ***violations of the Food Drug and Cosmetic (FD&C) Act and related Acts***."[3] (Emphasis added).

[3] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions

The violations noted in FDA Form 483s are important. According to the FDA, "FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and ***significant***."[4] (emphasis added).

105. Plaintiffs obtained the FDA Form 483 as part of a FOIA request. The form shows that the FDA observed several CMC violations during the inspection, including violations regarding the lack of a potency assays to measure SkinTE's strength, purity, and quality, as well as violations related to the Company's manufacturing, processing, packing, and holding procedures.

106. The first violation from the Form 483 related to SkinTE's potency assay. In particular, the FDA noted the following violation:

> ***There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess***.
>
> Specifically, your firm has not performed and documented quantitative data that validates your process for SkinTE product to show consistent aseptic processing, aseptic tissue washing, and other relevant characteristics such tissue size, cell counts, or relevant skin cell type identification.
>
> Your Director of Quality has stated the process "is more of an art than a science" . . . .

(Emphasis added).

107. In other words, the Company did not have an adequate proposed potency assay. A potency assay is the quantitative measure of biological activity. Ideally, it measures the ability or capacity of the product to effect a given result. The traditional approach for assessing the potency of biological products is to develop a quantitative biological assay that measures the activity of the product related to its specific ability to effect a given result. Thus, the FDA's observation that the

[4] *Id.*

Company did not have procedures in place to ensure SkinTE had the "identity, strength, quality, and purity they purport or are represented to possess" meant that the Company did not have an adequate potency assay.

108. Defendants knew they would have to have a potency assay before submitting the SkinTE IND application and BLA. According to 12 CFR § 601.2(d), "Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements ***to ensure the continued safety, purity, and potency of such products***." (Emphasis added).

109. But Defendants ignored this and did not develop a potency assay for SkinTE before submitting the IND application in July 2021. This decision would delay the SkinTE IND and BLA process, as the FDA placed the SkinTE IND on clinical hold until the Company developed an adequate potency assay.

110. The second observation from the Form 483 explained that the Company's manufacturing process and operations were deficient. Specifically, the Form 483 noted: "Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations."

111. This observation was material to the eventual SkinTE IND application and BLA because an IND application must contain manufacturing information such as information related to the controls used for manufacturing the drug product. Therefore, Defendants should have ensured that the Company's manufacturing facility had suitable construction to facilitate cleaning, maintenance, and proper operations before submitting the SkinTE IND application. However, Defendants ignored this violation, which ultimately caused the clinical hold and delayed the SkinTE IND and BLA process.

112. The third observation from the FDA Form 483 explained that the Company's system for monitoring environmental conditions were deficient. Specifically, the third observation noted:

> Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
>
> Specifically, your firm does not adequately monitor the ISO 7 environment used as a processing room that houses [redacted] hoods for handling SkinTE product. On 21 July 2018, your Director of Manufacturing Operations stated that there is no growth promotion or positive controls executed for microbial growth plates used in environmental monitoring.
>
> Also, your firm is not collecting air and surface samples within the ISO 7 processing room on a routine basis and there is no written procedure for routine monitoring of the processing room since the samples tested on 20 April 2018 documented in "[redacted] Validation Plan.

113. Defendants also ignored this violation. The FDA's clinical hold noted that the Company's systems for monitoring environmental conditions were still deficient in 2021. In issuing the clinical hold, the FDA advised the Company that they had to resolve issues related to "bacteriostasis and fungistasis testing" before the clinical hold could be lifted. These issues seem to be related to the FDA's 2018 observation that the Company's "Aseptic processing areas are deficient." Aseptic is defined as "free from contamination caused by harmful bacteria, viruses, or other microorganisms" whereas bacteriostasis is defined as "inhibition of the growth of bacteria without destruction" and fungistasis is defined as "inhibition of the growth and reproduction of fungi without destroying them." Thus, the July 2018 observations and 2021 clinical hold issues both relate to the Company's ability to stop the growth of bacteria and fungus in certain areas of its manufacturing facility, demonstrating that Defendants ignored this violation for over three years.

114. The fourth observation from the FDA Form 483 noted violations related to the Company's processing and shipping of SkinTE. Specifically, the fourth observation noted:

> Additionally, data (without document identification or date) related to the viability of cells in SkinTE does not include the following documentation to establish as pertinent to commercial product:
> - Specific preparation data pertaining to incoming human tissue
> - Processing data such as batch record
> - Final package presentation or specifications
> - Specific dates of processing and storage
> - Identity of analytical equipment
> - Sample preparation such as reagent, stains, or storage
> - Prospective protocol and acceptance criteria

115. Defendants also ignored this violation for years. The FDA's clinical hold letter noted that in 2021 the Company still had issues related to SkinTE's "storage" and "delivery device." This appears to be the same issue identified by the FDA in July 2018 that the Company did not have documentation related to SkinTE's "storage" or its "final package presentation or specifications." Thus, Defendants failed to correct this issue for over three years.

116. The fifth observation from the FDA Form 483 noted, "The quality control unit lacks authority to fully investigate errors that have occurred. Specifically, your firm does not have a written procedure to define or document an acceptable quantity, identity, or trend of bioburden within the SkinTE product, above/outside of which a deviation or investigation would be initiated."

117. The sixth observation from the FDA Form 483 noted:

> Established laboratory control mechanisms are not followed and documented at the time of performance.
>
> Specifically, continuous or consistent temperature monitoring of microbial incubation samples for SkinTE product samples is not performed or documented. Between April 25th and July 9th, 2019, [redacted] temperature readings were [redacted] over the course of 75 days.
>
> Additionally, your Director of Manufacturing Operations stated that differential pressures for the processing room where SkinTE product is handled inside [redacted], is not documented and there is no written

> procedure for such record. [Redacted] batches have been produced since 25 April 2018.

118. The seventh observation from the FDA Form 483 noted, "Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions. Specifically, cleaning is not performed for [redacted] processing SkinTE inside the ISO 7 room."

119. The seventh observation is related to the third observation, which noted that the Company's system for monitoring environmental conditions were deficient. These issues were present in 2021, when the FDA's clinical hold noted that the Company had to resolve issues related to "bacteriostasis and fungistasis testing" before the clinical hold could be lifted. These issues seem to be related to the FDA's observation that the Company's "Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions." Aseptic is defined as "free from contamination caused by harmful bacteria, viruses, or other microorganisms" whereas bacteriostasis is defined as "inhibition of the growth of bacteria without destruction" and fungistasis is defined as "inhibition of the growth and reproduction of fungi without destroying them." Thus, the July 2018 observations and 2021 clinical hold issues both relate to the Company's ability to stop the growth of bacteria and fungus in certain areas of its manufacturing facility—i.e., produce aseptic conditions.

120. The eighth observation from the FDA Form 483 noted, "Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations."

121. Defendants, as senior management of the Company, were aware of all the July 2018 violations. The purpose of an FDA Form 483 is to "notif[y] the company's management of

objectionable conditions."[5] After the inspection, "the FDA Form 483 is ***presented and discussed with the company's senior management***."[6] (Emphasis added). The FDA reads and discusses with senior management "[e]ach observation . . . so that there is a ***full understanding of what the observations are and what they mean***."[7] (Emphasis added). Thus, Defendants, as senior managers of the Company, would have had access to the Form 483 and been aware of the observations that were made during the inspection.

122. Moreover, according to AW1, directly after the FDA inspection, the Company had a "big meeting" to discuss the inspection and related issues.

123. Defendants also had a duty to address the violations. According to the FDA, a company is "responsible to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist."[8] However, Defendants failed to address the violations for several years.

124. Once the FDA told PolarityTE that SkinTE was a 351 HCT/P, Defendants should have resolved the July 2018 issues immediately to prepare for the IND application and BLA. The CMC issues identified in the Form 483 were necessary to a successful IND and BLA. An IND application must contain manufacturing and CMC information required to assure the safety, identity, quality, and strength (including potency) of the investigational product, and an acceptable manufacturing facility inspection is required before a BLA can issue. *See* 2 U.S.C. § 262(c) ("The

[5] FDA Form 483 Frequently Asked Questions, *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form%20483,FD%26C)%20Act%20and%20related%20Acts.
[6] *Id.*
[7] *Id.*
[8] *Id.*

Secretary shall approve a biologics license application" if, among other things, "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent"); *see also* 21 C.F.R. § 601.20(d) ("A biologics license shall be issued or a biologics license application approved only after inspection of the establishment(s) listed in the biologics license application and upon a determination that the establishment(s) complies with the standards established in the biologics license application and the requirements prescribed in applicable regulations.").

125. Based on this, Defendants knew that they would have to have adequate manufacturing controls and processes before submitting an IND application. Because the FDA had already told Defendants about significant CMC issues, including the lack of potency assays for SkinTE and that the Company's manufacturing controls and processes were deficient, Defendants should have resolved the CMC issues from July 2018 before submitting an IND application.

126. However, Defendants blatantly ignored the issues, despite public statements to the contrary, which ultimately caused the clinical hold and delayed the SkinTE IND and BLA.

V. DEFENDANTS MADE FALSE AND MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACT REGARDING THE COMPANY'S ABILITY TO MARKET AND SELL SKINTE AS A 361 HCT/P AND THE COMPANY'S MANUFACTURING FACILITY

127. This Class period begins on January 30, 2018. On that day, the Company filed its Annual Report for the fiscal year ended October 31, 2017 on Form 10-K with the SEC (the "2017 10-K"). The 2017 10-K was signed by Defendant Lough.

128. The 2017 10-K portrayed PolarityTE as a commercial stage company based on its ability to market and sell SkinTE under Section 361. The 2017 10-K stated that "PolarityTE is a ***commercial-stage*** biotechnology company and regenerative biomaterials company" and that

"SkinTE is ***commercially available*** for the repair, reconstruction, replacement and regeneration of skin . . . ." (Emphasis added).

129. The foregoing statements were false and misleading for failing to disclose that PolarityTE was only a commercial stage company because it had improperly registered SkinTE under Section 361, when in fact, SkinTE was appropriately registered under Section 351, which requires premarket approval from the FDA. Thus, PolarityTE was still a developmental stage company, since it was inevitable that the FDA would disagree with the Section 361 classification and require premarket approval under the Section 351 pathway before the Company could sell SkinTE.

130. The 2017 10-K promoted the Section 361 pathway as one of the Company's "competitive strengths," stating, in pertinent part:

> ***Efficient Regulatory Pathway***. We believe our products and product candidates, including SkinTE, are appropriately regulated by the FDA as 361 HCT/Ps, which provides us with the potential to register and list products with the FDA, and ***begin commercializing quickly and efficiently.*** Unlike products regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and/or the Public Health Service Act as drugs, devices, or biologics, which require multi-phase clinical trials and premarket approvals, our SkinTE product is regulated by the FDA as human cells or tissues intended for implantation. We are developing our additional pipeline candidates to be regulated as 361 HCT/Ps as well. ***361 HCT/Ps do not require premarket approval or other premarket authorization and may be lawfully marketed for appropriate human use in the United States following registration with the FDA***.

(Emphasis added).

131. Similarly, the 2017 Form 10-K explained that "the full commercial launch of SkinTE" was key to the Company's growth strategy.

132. The statements in ¶¶ 130 – 131 were false and misleading for failing to disclose that SkinTE was not properly registered under Section 361 and that, as a result, the Company's

ability to commercialize SkinTE under Section 361 was not sustainable since it was inevitable that the FDA would eventually disagree, and the Company would have to cease all commercial operations until SkinTE was approved under the Section 351 pathway.

133. On January 14, 2019, the Company filed its Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the fiscal year ended October 31, 2018 (the "2018 10-K"). The 2018 10-K was signed by Defendants Lough and Mann.

134. The 2018 10-K stated the following about the Company's commercial operations:

> SkinTE, our first tissue product, ***was registered with the United States Food and Drug Administration (FDA) in August 2017, and is now commercially available*** for the repair, reconstruction, replacement, and regeneration of skin in patients who have a need for treatment of acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts. ***We are pursuing a regional plan for commercial rollout that began in late October 2018, and we now have 24 sales representatives in the field marketing SkinTE***.
>
> * * *
>
> ***SkinTE is registered as a 361 HCT/P with the FDA pursuant to Section 361 of the Public Health Service Act and 21 CFR 1271.*** An HCT/P is defined as an article containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Products that qualify as 361 HCT/Ps are not subject to the FDA's pre-market clearance or approval requirements, but rather can be immediately listed for commercial use with the FDA and are then subject to post-market regulatory requirements such as compliance with current good tissue practices (cGTP), adverse event and deviation reporting, and post-market inspections by the FDA.

(Emphasis added).

135. The foregoing statement was false and misleading for failing to disclose that SkinTE was not properly registered under Section 361 and that, as a result, the Company's ability to commercialize SkinTE under Section 361 was not sustainable since it was inevitable that the

FDA would eventually disagree, and the Company would have to cease all commercial operations until SkinTE was approved under the Section 351 pathway.

136. The 2018 10-K stated the following about the Company's manufacturing at its Salt Lake City facility:

> We have designed and developed manufacturing processes and quality systems that allow us to receive a specimen, qualify the incoming tissue, process and manufacture the cell/tissue product, and perform outgoing quality control and quality assurance work prior to shipping. We believe that our ultra-clean dual-barrier system, which involves clean room structures containing fully-isolated and air-locked internal ISO 4 containment systems, allows us to move specimen and product in an efficient manner, while maintaining protective quality systems.

137. The foregoing statement was false and misleading because, at the time it was made, the Company's manufacturing process and quality systems were deficient. Specifically, the foregoing statement was false and misleading for failing to disclose that, in July 2018, the FDA observed several violations related to the Company's manufacturing processes and quality systems. As noted above, the FDA informed Defendants that the "[b]uildings used in the manufacture, processing, packing, or holding do not have the suitable construction to facilitate cleaning, maintenance, and proper operations" and that "areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations." Thus, contrary to the foregoing statement, the Company did not have adequate manufacturing and quality systems to perform outgoing quality control and quality assurance work prior to shipping. Similarly, the FDA told Defendants that the Company's system for monitoring environmental conditions was deficient. In the Form 483, the FDA noted that the Company "does not adequately monitor the ISO 7 environment used as a processing room that houses [redacted] hoods for handling SkinTE product." Thus, the Company's fully isolated and air locked containment systems did not allow them to move SkinTE in an efficient manner while maintaining protective quality systems.

138. The 2018 10-K also contained false and misleading statements and omissions in its disclosure of Risk Factors. Specifically, the 2018 10-K stated in its Risk Factors section that:

> ***We believe our FDA-registered SkinTE and OsteoTE products satisfy applicable criteria for regulation as a 361 HCT/P and are therefore exempt from FDA requirements for premarket approval or clinical studies.*** If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to these product candidates, and requires an Investigational New Drug application ("IND") or Investigational Device Exemption application ("IDE") for any of our product candidates, ***we may need*** to delay, abandon, or revise our current development plans, discontinue ongoing marketing, or recall products. The submission of an IND, Biologics License Applications ("BLA"), New Drug Application ("NDA"), or other medical device clearance or approval application would require us to compile significant amounts of data related to that regulatory process, as well as data from preclinical or clinical testing. We cannot guarantee that we will ever be able to secure such approvals, if required. Even if such approvals are obtained, regulation as a drug, biologic, or medical device would subject us to additional FDA post marketing requirements that are complex and involve substantial expense, such as compliance with drug, biologic, or medical device current Good Manufacturing Practice or quality system requirements.
>
> * * *
>
> By contrast, the FDA exempts 361 HCT/Ps from these requirements if they meet certain specified criteria. We believe that SkinTE and OsteoTE, meet the criteria for regulation as a 361 HCT/P rather than as a new drug or biologic or medical device and, therefore, we do not currently expect that these products will be subject to the requirement for an IND or IDE or FDA premarket review and approval. ***Thus, our financial and business plans assume that we will not need to seek or obtain premarket FDA approval or clearance for SkinTE*** or OsteoTE . . . .

(Emphasis added).

139. The foregoing statement was misleading for failing to disclose that the that SkinTE did not meet the definition of a 361 HCT/P, and that Lough suppressed any opposition from employees that SkinTE was registered under the wrong section.

140. On May 10, 2019, PolarityTE issued a press release announcing first calendar quarter 2019 results ("1Q19 Press Release"). The 1Q19 Press Release provided the following update on the July 2018 FDA inspection:

> The U.S. Food and Drug Administration (FDA) has closed out the July 2018 inspection of the Company's Salt Lake City, UT manufacturing facility, and classified the inspection as Voluntary Action Indicated, or "VAI." Based on FDA's definitions regarding its inspection classifications, a VAI classification means that while FDA found and documented certain conditions during its inspection, FDA is not prepared to take or recommend administrative or regulatory action with respect to such inspectional observations. As the Company has previously reported, following its July 2018 inspection, FDA issued certain inspectional observations on Form FDA 483. As is customary under FDA policy, now that the July 2018 inspection has been closed out, the FDA has released its Establishment Inspection Report, or "EIR." The EIR, like the Form 483, was drafted by the inspectors immediately following the inspection and is dated August 2, 2018. This is before the Company responded to any of the inspectors' initial observations. The Company responded to those observations and engaged in a productive dialog with the FDA. Following the Company's submission of its responses, FDA classified the July 2018 inspection of our Salt Lake City Manufacturing site as VAI. ***The Company is pleased that the initial inspection of its Salt Lake City, UT manufacturing facility has been closed out with a favorable inspection classification,*** and looks forward to continuing to manufacture its human cellular and tissue-based products, including SkinTE™, which is impacting patients' lives on a daily basis, as evidenced by recent presentations and publications of data.

(Emphasis added).

141. The foregoing statement was false and misleading because Defendants failed to disclose that, although the Company responded to the FDA Form 483, they did not resolve the underlying violations at the Salt Lake City facility, which is confirmed by the fact that many of the issues from the July 2018 inspection were still present in August 2021.

VI. THE TRUTH REGARDING SKINTE'S REGULATORY STATUS AND THE COMPANY'S ABILITY TO MARKET AND SELL SKINTE AS A 361 HCT/P IS PARTIALLY REVEALED

142. On April 21, 2020, the FDA informed the Company that FDA's preliminary assessment was that SkinTE did not meet the requirements to be regulated solely under Section 361. As a result, in a press release dated April 30, 2020, the Company told investors that it "has decided to pursue a plan to submit an investigational new drug application (IND) and thereafter a biologics license application (BLA) for SkinTE" based on "preliminary views expressed by FDA." The press release further stated:

> To focus on pursuit of the BLA, the Company plans to substantially reduce commercial operations and other functions to conserve capital and significantly decrease cash burn. ***FDA has not asked the Company to stop marketing SkinTE as a human cell, tissue, or cellular and tissue-based product regulated solely under Section 361 of the Public Health Service Act (i.e., a 361 HCT/P). SkinTE will remain available under a limited sales and marketing program, subject to the Company's future discussions with FDA***. The decision to focus on a BLA for SkinTE and limit commercial operations proactively addresses FDA feedback on the regulatory pathway for SkinTE, the high costs associated with maintaining a commercial footprint, and the headwinds associated with the COVID-19 pandemic.

(Emphasis added).

143. On this news, the Company's stock fell by $0.06 per share, or 5.50%, to close at $1.03 per share on April 30, 2020. The next day, the stock fell an additional $0.10 per share, or 9.71%, to close at $0.93 per share on May 1, 2020.

144. However, the April 30, 2020 press release concealed that the FDA did not only provide "feedback" but in fact issued a preliminary assessment was that SkinTE did not meet the requirements to be regulated solely under Section 361. Moreover, the statement in ¶ 142 was misleading because Defendants did not disclose that PolarityTE could ***only*** sell SkinTE going forward because the FDA's enforcement discretion policy was still in place. Defendants knew

that that once the enforcement discretion policy ended, they would have to stop all commercial sales until they obtained a license under the 351 pathway. Despite this, Defendants continued misleading investors into believing that the Company could sell SkinTE as a 361 HCT/P indefinitely when, in truth, the Company could only sell SkinTE for a finite period of time.

VII. DEFENDANTS MADE FALSE AND MISLEADING STATEMENTS REGARDING THE SKINTE IND AND BLA, AND CONTINUED MAKING FALSE AND MISLEADING STATEMENTS REGARDING THE COMPANY'S ABILITY TO MARKET AND SELL SKINTE AS A 361 HCT/P

145. On May 11, 2020, PolarityTE filed a quarterly report for the quarterly period ended March 31, 2020 with the SEC on Form 10-Q ("1Q20 10-Q"). The 1Q20 10-Q was signed by Defendants Seaburg and Patterson. The 1Q20 10-Q stated the following about the FDA developments and the Company's plan to pursue an IND and BLA:

> Following informal, voluntary discussions between us and the United States Food and Drug Administration (FDA), and preliminary views expressed by FDA received on April 21, 2020 regarding the regulatory pathway for SkinTE, the Company believes that it is prudent to submit an investigational new drug application (IND) and thereafter a biologics license application (BLA) for SkinTE. We are in the process of arranging meetings with FDA to determine the most appropriate development plan for a BLA submission. ***Since 2018 we have been actively engaged in a clinical development program***, which includes a completed SkinTE study in burn wounds, ongoing randomized controlled trials (RCTs) in repairing diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), and outcomes data from many of the approximately 700 SkinTE clinical cases. ***We intend to submit these data to FDA as potential candidates for inclusion in a clinical data package to support a BLA***.

(Emphasis added).

146. The foregoing statement was false and misleading for failing to disclose that the Company had ignored CMC issues identified by the FDA in July 2018 that would have to be resolved before any clinical development program could begin under the Section 351 pathway. As a result, the FDA was unlikely to accept any data from the Company's post-marketing "clinical

development program" since any data was obtained before the Company resolved necessary CMC work, including developing a potency assay for SkinTE.

147. The 1Q20 10-Q also stated the following about the Company's commercial operations:

> ***FDA has not asked us to stop marketing SkinTE pending submission or approval of a BLA. We plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting, both until November 2020***, which marks the end of a 36-month period of enforcement discretion that the Agency announced in final Guidance issued in November 2017 that it would generally observe unless there are reported or potential significant safety concerns, ***and beyond November 2020***. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA.

(Emphasis added).

148. The foregoing statement was misleading because the Company did not disclose that PolarityTE could only sell SkinTE because the FDA's enforcement discretion policy was still in place. Defendants knew that that once the enforcement discretion policy ended, they would have to stop all commercial sales until they obtained a license under the 351 pathway. Despite this, Defendants continued misleading investors into believing that the Company could sell SkinTE as a 361 HCT/P indefinitely when, in truth, the Company could only sell SkinTE for a finite period of time.

149. The 1Q20 10-Q also contained false and misleading statements and omissions in its disclosure of Risk Factors. Specifically, the 1Q20 10-Q stated in its Risk Factors section that:

> When SkinTE was registered and listed with the FDA, we believed SkinTE was appropriately regulated solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (i.e., as a so-called "361 HCT/P") and that, as a result, no premarket review or approval by the FDA was required. ***We still believe that SkinTE is appropriately regulated as a 361 HCT/P***. However, following informal, voluntary discussions between FDA and the Company, and preliminary views expressed by FDA received on April 21, 2020, ***we believe that the***

> ***FDA may disagree with our interpretation if we sought a formal designation of SkinTE's regulatory classification***, and that it therefore is prudent to pursue a strategy to file an investigational new drug application ("IND") and thereafter a biologics license application ("BLA") for SkinTE.
>
> * * *
>
> The preliminary assessment by the FDA that SkinTE appears to be a biological product that would be regulated under Section 351 of the Public Health Service Act will negatively impact our commercialization of the product and substantially increase the cost to us of regulatory compliance, all of which ***could adversely affect our results of operations and financial condition***. This same risk applies to any other product we may develop that we believe should be regulated as a 361 HCT/P but where the FDA may disagree with our interpretation of the applicable regulations.

(Emphasis added).

150. The foregoing statement was misleading because it framed the risk that the Company would have to switch from a 361 HCT/P to a 351 HCT/P as a possible future risk when, in fact, the risk had already materialized because the FDA already advised the Company that SkinTE was not properly registered under Section 361. Thus, Defendants knew that they would have to obtain premarket review and FDA approval under the Section 351 pathway. As a result, Defendants knew that their financial condition would be negatively affected since they would have to stop all commercial sales of SkinTE as soon as the enforcement discretion period ended.

151. During a conference call also on May 11, 2020, Seaburg provided further detail on the Company's decision to pursue a BLA for SkinTE, stating that the "catalyst for this decision was not a formal designation or final determination from the FDA," but instead was because the Company believed that "the BLA pathway for SkinTE will create a more valuable asset as a result of the clinical data that will support our submission and the benefits from regulatory exclusivity that can be gained through a BLA." Seaburg further stated that:

> ***[W]e're hopeful that we will be able to leverage our existing data to demonstrate the safety and effectiveness of SkinTE***. Over the past two

> years, we have been actively engaged in a clinical development program which includes a completed SkinTE study in burn wounds, our ongoing randomized control trials in diabetic foot ulcers and venous leg ulcers and outcomes data from many of the approximate 700 SkinTE clinical cases completed to-date. Importantly there have been zero reported adverse reactions to SkinTE since the launch of this product.
>
> We intend to submit these data set – this data to the FDA and are hopeful they will be considered in a clinical package to support a BLA.

(Emphasis added).

152. The foregoing statements were false and misleading for failing to disclose that the Company had ignored CMC issues identified by the FDA in July 2018, including that the Company lacked any procedures to establish SkinTE's identity, strength, quality, and purity (i.e., potency assays). The FDA placed the SkinTE IND on clinical hold in August 2021 based on, among other things, the lack of a potency assay for SkinTE. Thus, when Seaburg made the foregoing statement, the Company did not have existing data sufficient to meet FDA standards for the safety and effectiveness of SkinTE.

153. During the question-and-answer portion of the May 11, 2020 conference call, an analyst asked about the regulations of HCT/Ps. The analyst stated, "There are four criteria which are in the register in the CFR 1271 – 21 CFR 1271. Has your team looked at those criteria? And do you feel comfortable that you could still be considered 361 HCT/P product[]?" Defendant Hague responded:

> [W]e certainly feel like we have a good case for meeting those criteria. As we mentioned earlier FDA felt differently certainly in some certain areas. So going forward until we can have deeper discussions with FDA, we can't make a determination as [] how they're going to ultimately decide our ability to market this product going forward.

154. The foregoing statement was misleading because Defendants knew how the FDA was going to decide its ability to market SkinTE. Defendants knew, or were severely reckless is

not knowing, that SkinTE should have never been registered under Section 361. The FDA's preliminary assessment that SkinTE was not properly registered under Section 361 confirmed this knowledge, at which point Defendants knew that the Company could only market SkinTE after receiving FDA approval under the 351 pathway.

155. Defendant Hague also stated during the conference call that "right now our focus is to make sure we're doing everything necessary to obtain a BLA."

156. The foregoing statement was false and misleading because the Company was not doing "everything" necessary to obtain a BLA. A BLA can issue only after an acceptable manufacturing facility inspection and a determination by the FDA that the biological product meets the applicable requirements to ensure the continued safety, purity, and potency of such products. However, the FDA had already told Defendants that PolarityTE did not have the necessary procedures in place to ensure the continued safety, purity, and potency of SkinTE, *see* ¶ 106 above, and that the Company's manufacturing facility and processes were not up to FDA standards, *see* ¶ 110, 112, 114, 117, 118, 120 above. Because Defendants did not resolve these issues—which were known to them for years—they were not doing "everything" necessary to obtain a BLA.

157. On August 6, 2020, PolarityTE filed a quarterly report for the quarterly period ended June 30, 2020 with the SEC on Form 10-Q ("2Q20 10-Q"). The 2Q20 10-Q was signed by Defendants Seaburg and Patterson.

158. The 2Q20 10-Q provided further information on the FDA's "preliminary assessment" of SkinTE. But unlike the 1Q20 10-Q—which stated that the FDA ***may*** disagree with the 361 classification—the 2Q20 10-Q finally admitted that the FDA advised the Company that "SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act." Moreover, the 2Q20 10-Q no longer said that the Company "still believe[s] that

SkinTE is appropriately regulated as a 361 HCT/P." The Company provided no explanation for what had changed since the 1Q20 10-Q.

159. The 2Q20 10-Q also stated the Company reevaluated its regulatory approach based on, among other things, "the ***possibility*** the FDA could restrict our commercial sale of SkinTE in the future." (Emphasis added).

160. This statement was false or misleading because it was not merely a possibility that the FDA would restrict commercial sale of SkinTE. Instead, once the enforcement discretion period ended, it was ***certain*** that the FDA would restrict commercial sale of SkinTE until the Company obtained an approved BLA for SkinTE.

161. On November 9, 2020, the Company filed a quarterly report for the quarterly period ended September 30, 2020 with the SEC on Form 10-Q ("3Q20 10-Q"). The 3Q10-Q was signed by Defendants Seaburg and Patterson. The 3Q20 10-Q stated, in relevant part:

> In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat diabetic foot ulcers (DFUs), and we received written responses to our meeting request and questions in October 2020. ***FDA's responses included, among other things, feedback and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission***. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing randomized controlled trial (RCT) in DFUs has elements of an adequate and well-controlled study, but stated that it would not accept our ongoing post-marketing RCT in DFUs as one of the two adequate and well-controlled studies to support a future marketing application.
>
> * * *

> ***In the coming months we will pursue the preparation of an IND filing with FDA, which we believe we will be able to file in the second half of 2021. This effort will include, among other things, the completion of CMC and pre-clinical work to satisfy FDA requirements, interaction with FDA on additional indications, trials design, preparation and submission of the IND, and planning for clinical trial enrollment to begin as soon as we have an open IND***.

(Emphasis added).

162. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency of SkinTE and the Company's manufacturing facility. Thus, the Company was not "complet[ing] CMC . . . work to satisfy FDA requirements," and was not on track to file the IND in the second half of 2021.

163. The 3Q20 10-Q reported net revenues of $3.337 million for the three-month period ended September 30, 2020. The 3Q20 10-Q stated the following about revenue from SkinTE sales:

> For the three-month period ended September 30, 2020, net revenues from the regenerative medicine product segment are $1.156 million, which represents an increase of $0.317 million or 38% from the $0.839 million of net revenues recorded for the three months ended September 30, 2019. This change is attributable to an increase of 51% in the number of paid cases from 81 in the third quarter of 2019 to 122 in the third quarter of 2020, and to a lesser extent the higher average revenue per paid case we experienced in the third quarter of 2020 . . . .
>
> As noted above, we plan to submit to FDA an IND and BLA for SkinTE. We are in the process of preparing our IND submission and ***FDA has not asked us to stop marketing SkinTE pending submission or approval of a BLA***. FDA announced in revised final guidance issued in July 2020 that it would generally observe its practice of enforcement discretion established in prior guidance unless there are reported or potential significant safety concerns until May 31, 2021. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA, but ***we plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting***.

* * *

> ***We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending.*** Accordingly, management determined it was prudent under the circumstances discussed above to focus our commercialization effort on the territories where we have current and repeat users of SkinTE. As a result, in May 2020 we eliminated 40 positions in the regenerative medicine product segment, including 24 positions engaged in performing sales and marketing functions.

(Emphasis added).

164. The foregoing statements were false and misleading because the Company failed to adequately warn investors that the Company's net revenue from the regenerative medicine product segment—which accounted for 35% of total net revenue for the three months ended September 30, 2020—would soon go to zero. The foregoing statement was also misleading because the Company could sell SkinTE only because the FDA's enforcement discretion policy was still in place. Defendants knew that that once the enforcement discretion policy ended, they would have to stop all commercial sales until they obtained a license under the 351 pathway. Despite this, Defendants continued misleading investors—making statements such as "we plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting"—leading investors to believe that the Company could continue generating SkinTE sales while its IND application and BLA were pending, when in reality, the Company would not be able to sell SkinTE until the FDA approved a BLA.

165. That same day, PolarityTE hosted a conference call with investors and analysts. During that conference call, Defendant Seaburg "highlight[ed] three notable accomplishments," including:

> First, since announcing the decision to transition our regulatory pathway for SkinTE back in April, ***our team has made significant progress preparing for BLA***. We completed necessary data and patient outcomes that enabled us to submit a pre-IND briefing material to the FDA in August. And we received feedback from the FDA in October, and are actively developing a plan to submit an IND with multiple indications including DFUs, pressure

> ulcers, and acute wounds, which represents a multi-billion dollar market opportunity.

(Emphasis added).

166. The foregoing statement was false and misleading for failing to disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency of SkinTE and the Company's manufacturing facility. Thus, the Company was not making "significant progress" towards a BLA.

167. Defendant Seaburg also stated that the Company sought clarity from the FDA on three main areas of focus, "which were clinical, non-clinical, and chemistry, manufacturing and controls, or CMC." With regard to the CMC area of focus, Defendant Seaburg stated that following:

> With regards to the non-clinical and CMC subject matters, the agency's responses were consistent with industry guidance and confirmed our current strategy. ***We will continue our work to fully characterize the final SkinTE product in a way that allows us to identify, quantify and implement the key release assays required by FDA***. In parallel, we will complete any additional pre-clinical work as needed.
>
> * * *
>
> ***In the coming weeks and months, we will be undertaking the key activities to ensure timely IND filing in the second half of 2021. These will include the completion of the necessary CMC and preclinical work to satisfy FDA requirements*** . . . .

(Emphasis added).

168. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility—and thus, the Company was not on track to file the IND in the second half of 2021.

169. On February 10, 2021, the Company issued a press release providing a regulatory update. The press release stated:

> Over the last several months, the Company has had meaningful interactions with the FDA regarding the Company's planned IND for SkinTE. Through these interactions the Company gained valuable insight regarding the critical information it expects to include in the IND, and believes it remains on track to file the IND for SkinTE in the second half of 2021.

170. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility—and thus, the Company was not on track to file the IND in the second half of 2021.

171. On March 30, 2021, PolarityTE filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2020 ("2020 10-K"). The 2020 10-K was signed by Defendants Seaburg and Patterson.

172. The 2020 10-K stated the following about SkinTE sales activity:

> ***We continued to sell SkinTE as a 361 HCT/P in 2020 and into 2021 in reliance on our view that there is a reasonable basis for regulating SkinTE as a 361 HCT/P and also in reliance on the enforcement discretion position stated in the policy framework***. In May 2020, we effectuated a reduction in force within our regenerative medicine business segment to reduce historical monthly cash burn and preserve capital for pursuing the filing of an IND. Since then we have focused our commercial effort for SkinTE on the territories where we have current and repeat users of SkinTE.
>
> We have evaluated the question of whether the FDA may extend enforcement discretion on regenerative medical products, and as of the date of this report the FDA has not taken any action on extending enforcement discretion. ***Following the end of the FDA's period of enforcement discretion, we may need to cease selling SkinTE until the FDA approves a BLA***, and then we will only be able to market the product for indications

> that have been approved in a BLA. We cannot predict at this time when we may decide on continuing SkinTE sales because of the uncertainty around the decisions the FDA may make in this area.

(Emphasis added).

173. The 2020 10-K also touted the increase in net revenues for the fiscal year 2020, stating, in pertinent part: "Net revenues increased by 79% to $10.126 million in 2020. The increase in net revenues for sale of products was the result of a sales strategy adopted in May 2020 to focus on regions and facilities where we had repeat users of SkinTE." Net revenues from the regenerative medicine products was $3.730 million, or roughly 37% of the Company's total revenue.

174. Similarly, the 2020 10-K stressed the importance of SkinTE revenue, stating, in pertinent part:

> We have generated revenue from the sale of SkinTE as a 361 HCT/P product since 2018. In addition, we have generated revenue from our laboratory testing and research service business. Revenue from these activities has been helpful in lowering the rate at which we use capital obtained from external sources.
>
> Gross profit from the sale of SkinTE covered 5% of our total operating costs and expenses in 2020. ***However, if the FDA allows enforcement discretion for regenerative tissue products to expire at the end of May 2021, we may need to cease selling SkinTE until the FDA approves a BLA***, and then we will only be able to market SkinTE for the indications that have been approved in the BLA. Consequently, ***it is possible that SkinTE sales may not continue to contribute to our capital resources in 2022***. We are actively seeking opportunities to continue the process of reducing our operating expenses, and if SkinTE sales end in the future we intend to re-double our efforts to reduce costs of operations to make up for the loss of revenues.

(Emphasis added).

175. The statements in ¶¶ 172 – 174 were false and misleading because the Company failed to adequately warn investors that the Company's net revenue from the regenerative medicine product segment—which accounted for 37% of total net revenue for the fiscal year ended

December 31, 2021—would soon go to zero. The foregoing statements were also misleading because Defendants led investors to believe that they could continue marketing and selling SkinTE as a 361 HCT/P indefinitely when, in reality, the Company would have to stop selling SkinTE as soon as the enforcement discretion policy ended. Because the FDA enforcement discretion policy ended on May 31, 2021, there was no possibility that SkinTE sales could contribute to the Company's capital resources in 2022.

176. Further, in discussing the Company's "Plan for Advancing SkinTE," the 2020 10-K stated, in relevant part:

> [W]e decided in April 2020 to pursue the preparation and filing with the FDA of an IND and BLA for SkinTE. Consequently, in May 2020 we effectuated a reduction in force within our regenerative medicine business segment to reduce monthly cash burn. At the end of 2020 we had approximately 10 salespeople and six clinical science staff that supported the sales team. ***In the coming months we will pursue the preparation of an IND filing with the FDA, which we believe we will be able to file in the second half of 2021***.
>
> In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat DFUs, and we received written responses to our meeting request and questions in October 2020. ***FDA's responses included, among other things, feedback, and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission***. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing DFU RCT has elements of an adequate and well-controlled study but stated that it would not accept our ongoing post-marketing DFU RCT as one of the two adequate and well-controlled studies to support a future marketing application.

(Emphasis added).

177. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency of SkinTE and the Company's manufacturing facility—and thus, Defendants had not done the necessary work to avoid a clinical hold of the SkinTE IND application.

178. The 2020 10-K stated the following about the Company's manufacturing:

> Throughout 2020 we maintained at our facility in Salt Lake City, Utah, manufacturing processes and quality systems that allow us to receive a skin specimen, qualify the incoming tissue, process and manufacture the SkinTE tissue product, and perform outgoing quality control and quality assurance work prior to shipping. ***We validated our manufacturing process as being aseptic***. All SkinTE is manufactured within an ISO 5 isolator located within an ISO 7 cleanroom. ***Our processes are designed and validated to prevent the spread of communicable disease, and to prevent cross-contamination between samples. Our quality systems comply with current Good Tissue Practices ("cGTP") under 21 C.F.R. Part 1271***.
>
> In connection with the preparation of our IND we are making plans to modify our manufacturing practices and facility so that we comply with current Good Manufacturing Practices ("cGMP") under 21 C.F.R. Parts 210 and 211, and other applicable regulations, which are in addition to cGTP referenced above.

(Emphasis added).

179. The foregoing statement was false and misleading because it did not disclose that the FDA noted several manufacturing issues during their July 2018 inspection, many of which were still present in 2021, including issues related to antibiotics residuals and bacteriostasis and fungistasis testing.

180. The 2020 10-K also contained false and misleading statements and omissions in its disclosure of Risk Factors. Specifically, the 2020 10-K stated in its Risk Factors section that the Company's "ability to timely submit an IND or BLA to the FDA may depend on circumstances outside of our control."

181. This was false and misleading because issues that prevented timely submission of the IND application were well within Defendants' control, specifically the CMC issues that Defendants ignored for years.

182. The 2020 10-K Risk Factors section also falsely stated:

> We continue to market SkinTE as a 361 HCT/P product and under the FDA's policy of enforcement discretion (currently scheduled through May 2021) as we work to transition SkinTE to a Section 351 product. Our net revenues from SkinTE sales in 2020 were $3.7 million. ***Following the end of the FDA's period of enforcement discretion, we may need to cease selling SkinTE until the FDA approves a BLA***, and then we will only be able to market the product for indications that have been approved in a BLA. The loss of our ability to market and sell SkinTE would have an adverse impact on our revenues, financial condition, and results of operations.

(Emphasis added).

183. The foregoing statement was false and misleading because the Company failed to adequately warn investors that the Company's net revenue from the regenerative medicine product segment—which accounted for 37% of total net revenue—would soon go to zero. The foregoing statement was misleading because it framed the risk that the Company would have to stop marketing and selling SkinTE as a 361 HCT/P as a possible future risk when, in fact, the risk had already materialized. By that point, the FDA already advised the Company that SkinTE was not properly registered under Section 361. Thus, Defendants knew that they would have to obtain premarket review and FDA approval under the Section 351 pathway. As a result, Defendants knew that their financial condition would be negatively affected since they would have to stop all commercial sales of SkinTE as soon as the enforcement discretion period ended.

184. During the same day, PolarityTE hosted a conference call with investors and analysts. During that conference call, Defendant Hague stated:

> I am pleased to share the progress we've made towards our goal of submitting an IND for SkinTE in the second half of this year. As I described

> in our last earnings call, we received our initial pre-IND feedback from FDA in Q4. Since then, we have had other interactions with the agency that have given us additional clarity and confidence around our ongoing IND enabling activities.
>
> These activities remain specifically focused on three areas; CMC or Chemistry Manufacturing and Controls, pre-clinical and clinical. ***With regard to CMC, our team is making excellent progress towards characterizing SkinTE, which over the next few months should allow us to validate and implement a matrix of product release assays to meet FDA requirements. In parallel, we are making similarly strong progress on our transition to current good manufacturing practices or CGMP***.

(Emphasis added).

185. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility. Thus, the Company was not making "excellent progress" with the CMC work or making "strong progress" on its transition to acceptable manufacturing practices.

186. During the conference call, Defendant Seaburg mislead investors about the commercial operations of SkinTE, stating that "If enforcement discretion is not extended or the FDA does not make other accommodations for manufacturers of 361 products who are transitioning to a 351 product, we ***may*** need to need to see cease marketing SkinTE." (Emphasis added).

187. The foregoing statement was false and misleading because when the FDA's enforcement discretion period ended, the Company would be required to stop selling SkinTE until the FDA approved a BLA.

VIII. THE TRUTH REGARDING THE COMPANY'S ABILITY TO SELL SKINTE AS A 361 HCT/P IS REVEALED

188. On May 13, 2021, after market closed, the Company issued a press release announcing first quarter 2021 results and providing a business update on the Company's commercial operations. The press release revealed that the Company would be forced to cease ***all*** commercial sales of SkinTE by the end of the month after the FDA announced that it would not extend its enforcement discretion policy beyond May 31, 2021. The press release stated in pertinent part:

> In connection with this transition to the BLA pathway and based on the FDA's recent announcement that enforcement discretion related to 361 HCT/P products will not be extended beyond May 31, 2021, the Company will cease commercial sales of SkinTE and wind down commercial operations. The Company is planning to make substantial reductions in the costs associated with its commercial operations, which will mitigate the effect on cash flow resulting from the loss of SkinTE revenues.

189. On the same day, PolarityTE hosted a conference call with investors and analysts at 4:30 p.m. ET. During that conference call, Defendant Seaburg reiterated the Company's decision to cease all commercial sales, stating, "To be consistent with the FDA's enforcement discretion period ending on May 31, 2021, we will be winding down commercial sales of SkinTE."

190. On this news, PolarityTE's share price plummeted $0.26 per share, or approximately 21%, to close at $0.98 per share on May 14, 2021.

IX. DEFENDANTS CONTINUED MAKING FALSE AND MISLEADING STATEMENTS REGARDING THE SKINTE IND AND BLA

191. Defendants continued misleading investors about the SkinTE IND and BLA. For example, the May 13, 2021 press release stated that "PolarityTE continues to make strong progress with its pursuit of a BLA for SkinTE and is reiterating its guidance on the submission of an IND to the FDA in the second half of 2021."

192. The same day, PolarityTE hosted a conference call with investors and analysts. During that conference call, Defendant Hague stated, in pertinent part:

> Transitioning to regulatory, I am pleased to share that our team is continuing to make good progress, as we are now in the final phase of our IND-enabling activities. ***We remain on track to submit our IND in the second-half of this year, and are working diligently to accelerate that timeline as much as possible***. We're very much looking forward to engaging FDA as a part of the upcoming IND process, as we believe these interactions will inform and crystallize our future development plans for SkinTE.

(Emphasis added).

193. The statements in ¶¶ 191 – 192 were false and misleading because they did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility. Thus, the Company was not making "strong progress" on its pursuit of a BLA and was not on track to file the IND in the second half of 2021.

194. On July 26, 2021, PolarityTE issued a press release announcing that it had submitted the SkinTE IND to the FDA on July 23, 2021. The press release explained the IND and BLA process, stating in pertinent part:

> PolarityTE expects to receive feedback related to this IND submission from the FDA within approximately 30 days. This could result in an accepted IND or, if FDA raises questions regarding certain aspects of the Company's IND, correspondence from FDA (i.e., information requests and potentially a clinical hold if information requests or other issues are unresolved) after which PolarityTE would work with FDA in an effort to resolve any outstanding issues. The Company plans to take all necessary steps as it works towards achieving an accepted IND and expects to commence its first clinical trial under the IND soon after acceptance by FDA.
>
> Responses and feedback from the FDA can vary widely, and PolarityTE notes that other companies transitioning 361 HCT/Ps to the biologics regulatory pathway have experienced a variety of outcomes ranging from INDs accepted as submitted to responses and clinical holds from FDA requiring an interactive process with the Agency to obtain an accepted IND.

195. The foregoing statement was misleading because it did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018—specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility—which were necessary for approval of an IND application and BLA, and thus, it was unlikely that the FDA would approve the IND application.

196. Defendants knew they needed to resolve the FDA Form 483 issues before the SkinTE IND would be accepted. The Company's July 26, 2021 Current Report, filed with the SEC on Form 8-K, explained that "[p]rior to commencing a human clinical trial of a drug or biological product, an IND application, ***which contains . . . information about product chemistry, manufacturing, and controls*** [i.e., CMC] ***and a proposed protocol*** [i.e., potency assay], must be submitted to the FDA." (Emphasis added). Thus, the Company knew that the SkinTE IND application must contain satisfactory CMC and potency assay information.

197. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct known CMC issues, including those relating to the lack of a potency assay for SkinTE, for over three years.

198. On August 12, 2021, the Company issued a press release titled "PolarityTE Reports Second Quarter Financial Results and Provides Business Update." The press release stated, in pertinent part:

> In response to the IND submission the Company recently received requests from the FDA's Clinical and CMC reviewers for additional information and the Company provided initial responses to those requests. The Company appreciates the FDA's feedback and believes it is generally in line with what the Company anticipated following its pre-IND interactions with the FDA.
>
> * * *
>
> David Seaburg, Chief Executive Officer, commented, "***We have made great strides to position the Company for the future, most recently with the***

> ***submission of an IND, and I could not be more impressed by the organization's commitment to this achievement.*** We are also incredibly encouraged by the recent outreach and support from physicians and patients after ceasing sales of SkinTE, and we will work expeditiously in the pursuit of a Biologic License Application (BLA)."

(Emphasis added).

199. The foregoing statement was false and misleading because it did not disclose that the Company had failed to correct CMC issues before submitting the SkinTE IND and that, as a result, it was extremely likely that the FDA would place the SkinTE on clinical hold until the Company resolved the CMC issues.

200. The same day, PolarityTE hosted a conference call with investors and analysts. During that conference call, Defendant Seaburg stated:

> ***The progress we've made during the past several months to execute on our development plan for SkinTE reinforces my confidence that we have a team in place with the talent, dedication and experience required to achieve a successful BLA approva***l. Our recent IND submission was a critical first step to advance SkinTE through the regulatory process, which along with our commitment and focus on capital efficiency remains our highest priorities.

(Emphasis added).

201. The foregoing statement was false and misleading because it did not disclose that for over three years the Company had ignored CMC issues that were required for a successful SkinTE IND and BLA.

202. Also during the conference call, Defendant Hague stated: "In response to our submission, ***we recently received requests from FDA's clinical and CMC reviewers for additional information***, and we have provided responses to those requests earlier this week. I would categorize the feedback and questions we received as very helpful and generally in line with what we had anticipated." Defendant Hague continued, "***We feel that our responses and our***

revised clinical plan align well with FDA's feedback and further support our position on key elements of our IND." (Emphasis added).

203. The foregoing statement was false and misleading because Defendants did not disclose that the Company had failed to correct CMC issues identified by the FDA in July 2018, specifically, those relating to the safety, purity, and potency (i.e., assays) of SkinTE and the Company's manufacturing facility.

X. THE TRUTH REGARDING THE SKINTE IND AND BLA EMERGES

204. The truth regarding the SkinTE IND and BLA, as well as the Company's deficient CMC procedures, was partially revealed on August 24, 2021. On that day, before market hours, PolarityTE issued a press release providing an update on the SkinTE IND. The press release stated, in pertinent part:

> FDA provided feedback that certain Chemistry, Manufacturing, and Control (CMC) items need to be addressed prior to proceeding with a pivotal study. As a result, the study proposed in the IND has been placed on clinical hold. In accordance with standard practice and regulations, the FDA has advised that it will issue a clinical hold letter providing details on the basis for the hold to the Company by September 21, 2021.
>
> PolarityTE previously disclosed that there was the potential for a wide range of outcomes with respect to its SkinTE IND submission, including but not limited to a clinical hold, and the Company is already formulating a plan to address the issues identified by the FDA. Based on FDA feedback the Company is confident that the modifications made to its proposed clinical trial protocol in Wagner Grade 2 diabetic foot ulcers will enable this pivotal study to begin enrolling once the CMC issues are resolved.
>
> David Seaburg, Chief Executive Officer, commented, "In our July 26, 2021, press release regarding the IND submission we described the FDA's well-established procedures for IND submissions and we believe that the CMC issues FDA has identified are not necessarily unusual for companies working diligently to transition their products from 361 HCT/Ps to 351 HCT/Ps. We are actively working to address the issues identified by the FDA and our team plans to respond to the Agency's feedback as expeditiously as possible, and we are hopeful that we will be able to resolve any open items. Chronic cutaneous ulcers represent a substantial unmet

> medical need with significant economic burden, and we are grateful for FDA's engagement and eager to advance SkinTE through clinical studies and the regulatory process towards an eventual BLA submission."

205. On this news, Polarity TE's stock fell by $0.08 per share, or 9.52%, to close at $0.76 per share on August 24, 2021.

206. The full truth regarding the SkinTE IND and BLA, as well as the Company's deficient CMC procedures, was revealed on November 10, 2021. On that day, before market hours, PolarityTE issued a press release updating investors on the SkinTE IND clinical hold. Specifically, the press release stated, in pertinent part, "Based on recent informal interactions with FDA regarding certain chemistry, manufacturing, and control (CMC) issues related to the proposed potency assay for SkinTE®, the Company believes that its complete response to FDA's clinical hold correspondence will be submitted by year end."

207. The same day, PolarityTE filed a quarterly report for the quarterly period ended September 30, 2021 with the SEC on Form 10-Q ("3Q21 10-Q"). The 3Q21 10-Q revealed, for the first time, the specific CMC issues that needed to be addressed before the FDA would life the clinical hold. The 3Q21 stated, in pertinent part:

> On August 20, 2021, we were advised by the FDA that certain chemistry, manufacturing, and control ("CMC") items need to be addressed prior to proceeding with a pivotal study and, therefore, the FDA was placing the study on clinical hold and planned to issue a clinical hold letter to the Company by September 21, 2021. A clinical hold means that the pivotal study may not begin unless and until the clinical hold is lifted. On September 17, 2021, we received the clinical hold letter from the FDA, which described the FDA's request for information and modifications to the IND that are necessary for the clinical hold to be lifted, as well as non-clinical hold comments. ***The clinical hold issues that must be resolved before the clinical hold can be lifted involve, our proposed potency assay; drug product dosage, storage, shipping, and release specifications; antibiotics residuals; bacteriostasis and fungistasis testing; and delivery device***. Since our receipt of the clinical hold letter, we have engaged informally with the FDA regarding certain items, most notably the proposed potency assay for SkinTE. We have received helpful feedback from the

> FDA and are currently preparing a complete response to the clinical hold letter.

(Emphasis added).

208. During a conference call, which was held on November 10, 2021 at 8:30 a.m. ET, Defendant Hague answered a question about the SkinTE IND process, stating, in pertinent part:

> So the way this process unfolded is that, we submitted our IND on the 23rd of July. And then at that point, FDA had 30 days to come back to us with various questions, which they did do. So these information requests, we responded to those in detail, to provide clarity to the FDA. And ultimately, those responses were utilized as part of their review of our entire IND package.
>
> At the end of that 30-day period, they ultimately informed us that while, many of the issues that they had presented to us were addressed, they still had other key issues that they felt were not sufficiently addressed. And so that was what led to the clinical hold communication. We were communicated to verbally with regards to that, and then, ultimately, the final clinical hold letter was received on September 17th. And in that letter, they identified a list of specific hold issues that we needed to address.

209. On this news, the Company's stock fell by $0.07 per share, or 10.45%, to close at $0.60 per share on November 10, 2021.

210. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's stock, Plaintiffs and other Class Members have suffered significant losses and damages.

XI. ADDITIONAL ALLEGATIONS SUPPORTING SCIENTER

A. Additional Allegations Concerning Lough's Scienter

211. The fact that Defendant Lough invented SkinTE supports a strong inference of scienter. As the inventor, Lough understood the technology better than anyone. Specifically, he knew that SkinTE was never appropriately registered as a 361 HCT/P because the manufacturing process—which he developed—involved manipulating the skin and adding growth factors to

create a paste that no longer possesses the relevant characteristics of skin. The addition of growth factors and manipulation of the skin into a paste were clearly prohibited under Section 361. Thus, Lough knew that the product did not meet the requirements under Section 361.

212. Lough's scienter can also be inferred from the fact that he suppressed any mention that SkinTE was registered under the wrong section. According to AW1, Lough was adamant that SkinTE was a 361 HCT/P and "was very head strong from the very beginning about not pursuing the BLA, and sticking to their guns about being a 361 [HCT/P]." According to this AW1, Lough did not like to hear anyone tell him the product did not fit the 361 category and, if anyone disagreed with him, Defendant Lough would "chop their head off."

213. Further supporting the inference of Lough's scienter is the numerous red flags he received regarding the fact that SkinTE was not properly a 361 HTC/P. Employees and investors repeatedly tried to tell Lough that SkinTE was registered under the section, but he intimidated and suppressed any mention of this. According to AW1, Lough was "pretty arrogant about what their regulatory status was." AW1 said that one investor who "had taken a massive position" and "had the ear of important people at the Company" tried to convince Lough to have the Company conduct clinical trials for an eventual BLA, just in case the FDA later disagreed with the 361 HCT/P classification," but Lough did not want to hear it.

214. Lough's scienter can be inferred from his position as CEO. Lough was the Company's CEO during the FDA's inspection of the Salt Lake City facility in July 2018. Thus, he was aware of the CMC issues identified by the FDA in the Form 483. The purpose of an FDA Form 483 is to "notif[y] the company's management of objectionable conditions." After an inspection, "the FDA Form 483 is presented and discussed with the company's senior management." The FDA reads and discusses with senior management "[e]ach observation . . . so

that there is a full understanding of what the observations are and what they mean." Thus, as CEO, Lough would have discussed each observation with the FDA and had a full understanding of each violation. He also would have understood that the Company would have to resolve these issues before successfully submitting an IND application or BLA.

215. Lough's scienter can also be inferred from the Board's abrupt decision to place him on administrative leave and thereafter remove him from the Company. This abrupt firing, which the Company never fully explained to investors, caused the SEC to issue a subpoena for documents concerning the unusual circumstances under which the Company placed Lough on paid administrative leave. Directly after Lough's firing, employees were able to openly discuss that SkinTE was registered under the wrong section. Thus, it can be inferred that Lough was aware of that SkinTE was registered under the wrong section.

216. Lough's scienter can be inferred from the small size of the Company. As of December 31, 2020, PolarityTE had approximately 80 full-time employees and five part-time employees, all of whom are in the United States. Due to the small size of the company, Lough was aware of SkinTE's registration status and the Company's CMC issues.

217. Lough's scienter can be inferred from the fact that SkinTE was the Company's only commercially available product and represented a significant portion of the Company's total revenue. For the fiscal year ended December 31, 2020, SkinTE sales accounted for 37% of the Company's total net revenues. For the fiscal year ended December 31, 2019, SkinTE sales accounted for 42% of the Company's total net revenues.

B. Additional Allegations Concerning Seaburg's Scienter

218. Seaburg's scienter can be inferred from the small size of the Company. As of December 31, 2020, PolarityTE had approximately 80 full-time employees and five part-time

employees, all of whom are in the United States. Due to the small size of the company, Seaburg was aware of SkinTE's registration status and the Company's CMC issues.

219. Seaburg's scienter can also be inferred from the fact that SkinTE was the Company's only commercially available product and represented a significant portion of the Company's total revenue. For the fiscal year ended December 31, 2020, SkinTE sales accounted for 37% of the Company's total net revenues. For the fiscal year ended December 31, 2019, SkinTE sales accounted for 42% of the Company's total net revenues.

220. Seaburg's role as a member of the Office of the Chief Executive supports a strong inference of scienter. In August 2019, the Board appointed Seaburg to serve as a member of the Office of Chief Executive after removing Lough as CEO. The Company stated that the purpose of the Office of Chief Executive was to address the immediate business needs of the Company as the Company transitions from product development of SkinTE to product commercialization. At that time, the "immediate business need" of the Company involved determining how to transition from a 361 HCT/P to a 351 HCT/P. As AW3 stated, in the summer and fall of 2019, there were ongoing discussions within the Company that SkinTE was registered under the wrong section and that the Company would have to change its regulatory path. These discussions were going on amongst directors and vice presidents in Regulatory, Quality, Manufacturing, and R&D, who attended meetings to discuss the regulatory change. By December 2019, the conversation had moved into more distinct planning. Thus, as the de facto CEO, Seaburg knew, or was severely reckless in not knowing, SkinTE was not properly registered under Section 361 and that the Company would have to change regulatory paths.

221. Searburg's role as CEO also supports a strong inference of scienter. Seaburg was the Company's CEO from March 31, 2020 until August 2021. As the CEO, Seaburg was

responsible for, among other things, making major corporate decisions and managing the overall operations and resources of the Company. During that time, the Company was transitioning to a commercial stage company after the FDA advised it that SkinTE was not properly registered as a 361 HCT/P. This was the most important issue facing the Company at the time, since SkinTE was the Company's most important and only commercially available product. Thus, Seaburg's main job was managing the successful submission of the SkinTE IND application. As such, Seaburg knew, or was severely reckless in not knowing, the CMC issues that the Company needed to resolve before submitting the SkinTE IND application.

222. There's a strong inference of scienter because Seaburg was aware of red flags showing that the Company had significant CMC issues. As CEO, Seaburg has access to correspondence with the FDA, including the Form 483, which clearly identified CMC issues that would need to be addressed before any successful IND application or BLA. Seaburg was aware of these CMC issues but did nothing, supporting a strong inference of scienter.

C. Additional Allegations Concerning Patterson's Scienter

223. Patterson's scienter can be inferred from his position as Vice President of Finance during the FDA's inspection of the Salt Lake City facility in July 2018. As a member of senior management, Patterson would have discussed each observation with the FDA and had a full understanding of each violation. He also would have understood that the Company would have to resolve these issues before successfully submitting an IND application or BLA. The purpose of an FDA Form 483 is to "notif[y] the company's management of objectionable conditions." After an inspection, "the FDA Form 483 is presented and discussed with the company's senior management." The FDA reads and discusses with senior management "[e]ach observation . . . so

that there is a full understanding of what the observations are and what they mean." Thus, as senior management, Patterson was aware of the CMC issues.

224. Patterson's role as Vice President of Finance also supports a strong inference that he was aware that SkinTE was registered under the wrong section. Patterson was the Vice President of Finance in the summer and fall of 2019, when there were ongoing discussions within the Company that SkinTE was registered under the wrong section and that the Company would have to change its regulatory path. These discussions were going on amongst directors and vice presidents in Regulatory, Quality, Manufacturing, and R&D, who attended meetings to discuss the regulatory change. By December 2019, the conversation had moved into more distinct planning. As Vice President of Finance, Patterson knew, or was severely reckless in not knowing, that SkinTE was not properly registered under Section 361 and that the Company would have to change regulatory paths. This change would severely affect the Company's finances since SkinTE was the Company's only commercially available product and contributed a material amount to the Company's net revenue.

225. Patterson's scienter can be inferred from the small size of the Company. As of December 31, 2020, PolarityTE had approximately 80 full-time employees and five part-time employees, all of whom are in the United States. Due to the small size of the company, Patterson was aware of SkinTE's registration status and the Company's CMC issues.

226. Patterson's scienter can also be inferred from the fact that SkinTE was the Company's only commercially available product and represented a significant portion of the Company's total revenue. For the fiscal year ended December 31, 2020, SkinTE sales accounted for 37% of the Company's total net revenues. For the fiscal year ended December 31, 2019, SkinTE sales accounted for 42% of the Company's total net revenue.

D. Additional Allegations Concerning Mann's Scienter

227. Mann was the Company's CFO during the FDA's inspection of the Salt Lake City facility in July 2018. Thus, Mann was aware of the CMC issues identified by the FDA in the Form 483. The purpose of an FDA Form 483 is to "notif[y] the company's management of objectionable conditions." After an inspection, "the FDA Form 483 is presented and discussed with the company's senior management." The FDA reads and discusses with senior management "[e]ach observation . . . so that there is a full understanding of what the observations are and what they mean." Thus, as senior management, Mann would have discussed each observation with the FDA and had a full understanding of each violation. He also would have understood that the Company would have to resolve these issues before successfully submitting an IND application or BLA.

228. Mann's scienter can be inferred from his role as CFO in the summer and fall of 2019, when there were ongoing discussions within the Company that SkinTE was registered under the wrong section and that the Company would have to change its regulatory path. These discussions were going on amongst directors and vice presidents in Regulatory, Quality, Manufacturing, and R&D, who attended meetings to discuss the regulatory change. By December 2019, the conversation had moved into more distinct planning. As CFO, Mann knew, or was severely reckless in not knowing, that SkinTE was not properly registered under Section 361 and that the Company would have to change regulatory paths. This change would severely affect the Company's finances since SkinTE was the Company's only commercially available product and contributed a material amount to the Company's net revenue.

229. Mann's scienter can be inferred from the small size of the Company. As of December 31, 2020, PolarityTE had approximately 80 full-time employees and five part-time

employees, all of whom are in the United States. Due to the small size of the company, Mann was aware of SkinTE's registration status and the Company's CMC issues.

230. Mann's scienter can also be inferred from the fact that SkinTE was the Company's only commercially available product and represented a significant portion of the Company's total revenue. For the fiscal year ended December 31, 2020, SkinTE sales accounted for 37% of the Company's total net revenues. For the fiscal year ended December 31, 2019, SkinTE sales accounted for 42% of the Company's total net revenue

E. Additional Allegations Concerning Hague's Scienter

231. Hague's scienter can be inferred from his role as a member of the Office of the Chief Executive. In August 2019, the Board appointed Hague to serve as a member of the Office of Chief Executive after removing Lough as CEO. The Company stated that the purpose of the Office of Chief Executive was to address the immediate business needs of the Company as the Company transitions from product development of SkinTE to product commercialization. At that time, the "immediate business need" of the Company involved determining how to transition from a 361 HCT/P to a 351 HCT/P. As AW3 stated, in the summer and fall of 2019, there were ongoing discussions within the Company that SkinTE was registered under the wrong section and that the Company would have to change its regulatory path. These discussions were going on amongst directors and vice presidents in Regulatory, Quality, Manufacturing, and R&D, who attended meetings to discuss the regulatory change. By December 2019, the conversation had moved into more distinct planning. Thus, as the de facto CEO, Hague knew, or was severely reckless in not knowing, SkinTE was not properly registered under Section 361 and that the Company would have to change regulatory paths.

232. Hague's scienter can also be inferred from his role as COO and CEO. Hague was the Company's COO from April 2019 until August 2021, when he assumed the role of CEO. As the COO, Hague was responsible for, among other things, overseeing the operational functions of the Company. During that time, the Company was transitioning to a commercial stage company after the FDA advised it that SkinTE was not properly registered as a 361 HCT/P. This was the most important operational function for the Company at the time, as SkinTE was the Company's most important and only commercially available product. Thus, Hague would have been responsible for ensuring that the Company's operations were up to FDA standards before submitting the SkinTE IND application. As such, Hague knew, or was severely reckless in not knowing, the CMC issues that the Company needed to resolve before submitting the SkinTE IND application.

233. Hague's scienter can be inferred from the small size of the Company. As of December 31, 2020, PolarityTE had approximately 80 full-time employees and five part-time employees, all of whom are in the United States. Due to the small size of the company, Hague was aware of SkinTE's registration status and the Company's CMC issues.

234. Hague's scienter can also be inferred from the fact that SkinTE was the Company's only commercially available product and represented a significant portion of the Company's total revenue. For the fiscal year ended December 31, 2020, SkinTE sales accounted for 37% of the Company's total net revenues. For the fiscal year ended December 31, 2019, SkinTE sales accounted for 42% of the Company's total net revenue.

XII. PLAINTIFFS' CLASS ACTION ALLEGATIONS

235. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all those who purchased or otherwise acquired PolarityTE

securities during the Class Period (the "Class") and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company at all relevant times, members of their immediate families, and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

236. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, PolarityTE securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by PolarityTE or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

237. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

238. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

239. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- Whether the federal securities laws were violated by Defendants' acts as alleged herein;

- Whether statements or omissions made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of PolarityTE;

- Whether the Individual Defendants caused PolarityTE to issue false and misleading financial statements during the Class Period;

- Whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- Whether the prices of PolarityTE during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- Whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

240. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

241. Plaintiffs and the Class are entitled to a presumption of reliance pursuant to the fraud-on-the-market doctrine because the Company's common stock traded in an efficient market during the Class Period, in that, among other things:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- The Company's common stock met the requirements for listing, and was listed and actively traded, on NASDAQ, a highly efficient, electronic stock market;

- As a regulated issuer, the Company filed periodic public reports with the SEC;

- The Company regularly communicated with public investors by means of established market communication mechanisms, including through regular dissemination of Current Reports in their SEC filings;

- The Company's shares were liquid and traded with moderate to heavy volume during the Class Period. On average, approximately 6,680,201 million shares of the Company's common stock, or roughly 17.41% of the Company's total shares outstanding, were traded weekly, permitting a very strong presumption that its shares traded on an efficient market;

- The Company traded on NASDAQ and was covered by at least 10 securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports were publicly available and entered the public marketplace;

- The Company traded on NASDAQ and there are at least 26 market makers that make a market in PolarityTE's stock;

- Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period;

- PolarityTE was eligible to file and did file a Registration Statement under Form S-3; and

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities.

242. Based on the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

243. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

XIII. NO SAFE HARBOR

244. The statutory safe harbor provision for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements alleged herein. Many of the specific statements alleged herein were not identified as "forward-looking statements" when made,

and thus are not entitled to protection under the safe harbor provision. Additionally, to the extent that there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements alleged herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

245. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

246. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

247. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class

members, as alleged herein; (ii) artificially inflate and maintain the market price of PolarityTE securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire PolarityTE securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

248. Pursuant to the above plan, scheme, conspiracy, and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for PolarityTE securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about PolarityTE's finances and business prospects.

249. By virtue of their positions at PolarityTE, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

250. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers

and/or directors of PolarityTE, the Individual Defendants had knowledge of the details of PolarityTE's internal affairs.

251. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of PolarityTE. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to PolarityTE's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of PolarityTE securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning PolarityTE's business and financial condition which were concealed by defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired PolarityTE securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

252. During the Class Period, PolarityTE securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of PolarityTE securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and

the Class, the true value of PolarityTE securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of PolarityTE securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

253. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly, or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

254. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

255. Plaintiffs repeat and reallege each and every allegation contained above as though set forth in full herein.

256. During the Class Period, the Individual Defendants participated in the operation and management of PolarityTE, and conducted and participated, directly and indirectly, in the conduct of PolarityTE's business affairs.

257. Because of their positions of control and authority as senior officers and/or directors of the Company, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings which PolarityTE disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants

exercised their power and authority to cause PolarityTE to engage in the wrongful acts complained of herein. Therefore, the Individual Defendants were "controlling persons" of PolarityTE within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of PolarityTE securities during the Class Period.

258. Each of the Individual Defendants acted as a controlling person of PolarityTE. By reason of their senior management positions and/or being directors of PolarityTE, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, PolarityTE to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of PolarityTE and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

259. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for violations committed by PolarityTE.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

A. Determining that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: February 21, 2022

JAMES DODGE RUSSELL & STEPHENS P.C.

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CERTIFICATE OF SERVICE

I, Mark F. James, hereby certify that this document was filed through the CM/ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on the 21st day of February 2022.

/s/ Mark F. James
Mark F. James